A. G. Engstrom — January 11, 1973 — W. Kirkwood Kelley #32

Cleveland

cc: Donald Kosel - Tonka
Jim Johnson - Minneapolis
J. G. Kingston - DPJRC

HEAVY METALS - STATUS UNDER CURRENT REGULATIONS

There are two broad classes of uses to be covered - food packaging and protective/decorative coatings. Food packaging materials usually come under FDA regulations and the only safe procedure for metals such as lead, cadmium and selenium is to establish that there is no migration to the food under the specific use conditions. If there is no migration, then the packaging material is not a food additive and is not subject to the FDA indirect additives regulations. If the packaging material is to be used in a plant under USDA inspection, it is necessary to obtain approval from the Animal and Poultry Health Inspection Service (APHIS formerly known as BID or PHS) for each specific product and use. The same data is required to support a no migration position, and the data must be submitted to USDA for review.

The use of the subject heavy metals in protective/decorative coatings is being questioned under the provisions of the Federal Hazardous Substances Act, formerly known as the Federal Hazardous Substances Labeling Act. While many other substances are being regarded with suspicion, attention has focused on the metals, particularly mercury and lead. The heavy metals referred to are those identified and covered in an industry specification (ANSI Z66.1-1964 - Coatings from surfaces which might be chewed by children). The surfaces are those of children's furniture, toys and interiors in dwellings. The dry film solids shall contain not more than 1% lead; shall contain not more than 0.06% total of Sb, As, Cd, Hg and Se; and shall not contain Ba compounds of which the water soluble Ba content exceeds 1% of the total Ba. The portion of this standard relating to lead content of 1% maximum is obsolete and is pre-empted by the FDA regulation, Section 191.9 specifying 0.5% maximum for lead.

There are no really usable FDA regulations relating to any of these metals in contact with food. One significant petition has been filed on selenium by the American Feed Manufacturers Association on June 17, 1971. This petition asks that selenium be approved for use in certain animal feeds at levels of less than 1 ppm.

GLD007102

FDA published a proposal on November 2, 1971 for special labeling of paints containing (a) more than 0.5% lead; or (b) more than 0.05% of Sb, As, Cd, Hg, or; or (c) with water soluble Ba content above 1% of the total Ba. Also on November 2, 1971, a petition by a consumer group was published asking to have lead-containing paints and other materials banned as hazardous substances.

On February 19, 1972, FDA published a request for data on the amounts of heavy metals in paints being used on surfaces accessible to children. It was understood that this request was made because FDA did not have sufficient information available to write a regulation. The National Paint and Coatings Association and several other trade organizations had been in contact with FDA following the November 2, 1971 publication and had given FDA the details of plans to obtain information on a number of the heavy metals including all of those referred to above. Some individual firms had also informed FDA that animal studies were contemplated and would require some time to complete.

On March 11, 1972, FDA published the findings on the two November 2, 1971 proposals and stated that further information is required before a final order can be written regarding the use in paints of the metals other than lead. An amendment to Section 191.9 was included banning paints containing more than 0.5% lead effective January 1, 1973 and paints containing more than 0.06% lead effective January 1, 1974.

On August 11, 1972, FDA published a summary of comments received on the March 11, 1972 order and concluded that the effective date of the paragraph relating to the 0.06% lead should be stayed and would be the subject of a separate document at a later date. Thus far, no such document has been published and we do not expect any for at least a year.

On December 5, 1972, FDA published the proposed exemption for seven classes of paints as requested by PMCA and also published the text of the petition submitted by PMCA. The latest action by FDA is a proposed exemption on January 4, 1973 which covers artist's paints and related materials as the eighth class exempted from the March 11, 1972 order.

The above covers the important developments and you will note that at present there are no specific regulations other than those on lead and mercury. We do expect a regulation similar to ANSI Z66.1-1964 but not for some time, perhaps a year. When the proposal is issued, we believe that there will be requests for exemption of certain classes of paints and for artist's paints.

Copies of the FDA regulations and proposals mentioned above are attached. Please give me a call if there is any question on any of the above.

ACE:cb
Encls.

A. C. Engstrom

GLD007101

notice or other public procedure has no precluded promulgation of the foregoing rule since it is found that the giving of such notice would prevent the due and timely administration of the Packers and Stockyards Act and would, therefore, be impracticable and contrary to the public interests. There is no legal warrant or justification for not depositing promptly a stockyard which is no longer within the definition of that term contained in the Act.

The foregoing is in the nature of a rule granting an exemption or relieving a restriction and, therefore, may be made effective in less than 30 days after publication in the FEDERAL REGISTER. This notice shall become effective upon publication in the FEDERAL REGISTER (6-17-71).

(42 Stat. 159, as amended and supplemented; 7 U.S.C. 181 et seq.)

Done at Washington, D.C., this 10th day of June 1971.

G. H. HOPPER,
Chief, Registrations, Bonds, and Reports Branch, Livestock Marketing Division.

[FR Doc.71-8517 Filed 6-16-71;8:50 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

AMERICAN FEED MANUFACTURERS ASSOCIATION, INC.

Notice of Filing of Petition for Food Additive Selenium

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a food additive petition (MF 3433V) has been filed by American Feed Manufacturers Association, Inc., 1725 K Street NW., Washington, D.C. 20006, proposing the establishment of a food additive regulation (21 CFR Part 121, Subpart C) to provide for the safe use, as a nutrient, of selenium from sodium selenite or sodium selenate in the feed of chickens, turkeys, and swine so that the total selenium content in complete feed does not exceed 0.25 part per million in feed for chickens and swine or 0.35 part per million in feed for turkeys. The premix which is incorporated into the feed is to be marked to indicate the presence of added selenium in the premix and the finished feed.

Dated: June 4, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-8474 Filed 6-16-71;8:46 am]

[DESI 6151]

CERTAIN PREPARATIONS CONTAINING DIHYPRYLONE OR PIPAZETHATE HYDROCHLORIDE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs:

1. Sedulon Syrup containing dihyprylone and extract of thyme; Roche Laboratories, Division Hoffmann-LaRoche, Inc., Roche Park, 340 Kingsland Street, Nutley, New Jersey 07110 (NDA 6-151).

2. Theratuss Tablets containing pipazethate hydrochloride; E. R. Squibb and Sons, 909 Third Avenue, New York, New York 10022 (NDA 12-820).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that these drugs are possibly effective for the labeled indications relating to the relief of coughs.

B. *Marketing status.* Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as possibly effective may be continued for 6 months as described in paragraphs (d), (e), and (f) of the notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273).

A copy of the Academy's report has been furnished to each firm referred to above. Any other interested person may obtain a copy by request to the Food and Drug Administration, Press Relations Office (CE-200), 200 C Street SW., Washington, D.C. 20204.

Communications forwarded in response to this announcement should be identified with the reference number DESI 6151, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original new drug applications: Office of Scientific Evaluation (BD-100), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-5), Bureau of Drugs.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: May 20, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-8475 Filed 6-16-71;8:46 am]

[DESI 8804]

ERYTHROMYCIN TOPICAL OINTMENTS

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following preparations of erythromycin ointment for topical use:

1. Erythrocin 1 Percent Ointment, containing erythromycin; Abbott Laboratories, 14th and Sheridan Road, North Chicago, Illinois 60064 (NDA 50-184).

2. Ilotycin Ointment, containing erythromycin; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 60-646).

The Food and Drug Administration concludes that the above listed drugs are possibly effective for their labeled indications.

Preparations containing erythromycin are subject to the antibiotic certification procedures pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act.

To allow applicants time to obtain and submit date to provide substantial evidence of the effectiveness of the drugs in those conditions for which they have been evaluated as possibly effective, batches of these drugs which bear labeling with those indications will be accepted for release or certification by the Food and Drug Administration for a period of 6 months after publication of this announcement in the FEDERAL REGISTER.

To be acceptable for consideration in support of the effectiveness of a drug, any such data must be previously unsubmitted, well organized, and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for the approval of the claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

At the end of the 6-month period, any such data will be evaluated to determine whether there is substantial evidence of

be held confidential and a determination is made that a proper showing in support of the request has been made on the grounds that its disclosure could adversely affect such person by disclosing information in the nature of trade secrets or commercial or financial information obtained from any person and privileged or confidential. If it is determined that a proper showing has been made in support of the request, the material will be held confidential; otherwise, notice will be given of denial of such a request and an opportunity afforded for withdrawal of the submission. Requests for confidential treatment will be held confidential (7 CFR 1.27 (c)).

Comments on the proposal should bear a reference to the date and page number of this issue of the FEDERAL REGISTER.

Done at Washington, D.C., on October 27, 1971.

KENNETH M. MCENROE,
Deputy Administrator, Meat and Poultry Inspection Program.

[FR Doc.71-15887 Filed 11-1-71;8:47 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 27, 31]

CERTAIN ORANGE JUICE PRODUCTS

Extension of Time for Filing Comments on Proposals Regarding Stayed Identity Standards

The notice published in the FEDERAL REGISTER of September 9, 1971 (36 F.R. 18098), proposing to revise the stayed standards for the diluted orange juice beverages (§§ 27.120, 27.121, 27.122) and proposing establishment of additional identity standards for certain related products, provided for the filing of comments within 60 days after said date.

The Commissioner of Food and Drugs has received a request for a 30-day extension of such time and, good reason therefor appearing, the time for filing comments on the subject proposals is hereby extended to December 8, 1971. Received comments may be seen in the office of the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, during working hours, Monday through Friday.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055, as amended, 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: October 15, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-15908 Filed 11-1-71;8:45 am]

[21 CFR Part 1481]

COMBINATION DRUG CONTAINING NEOMYCIN SULFATE AND AMPHOTERICIN FOR ORAL USE

Proposed Revocation of Provisions for Certification

In the FEDERAL REGISTER of July 2, 1970 (35 F.R. 10793; DESI 11212), the Commissioner of Food and Drugs announced the conclusions of the Food and Drug Administration following evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on a certain oral preparation containing neomycin sulfate and nystatin. The drug was regarded as lacking substantial evidence, as defined in the Federal Food, Drug, and Cosmetic Act, that it is effective as a fixed combination for its claimed clinical effect and that each component of the drug contributes to the total effects claimed for such drug.

In addition to the section of the antibiotic drug regulations describing conditions for certification of such preparations, another section describes conditions for certification of a related drug, Fungizone Tablets, containing neomycin sulfate and amphotericin B. An approved Form 5 antibiotic drug application (NDA 60-514) is held for this drug by E. R. Squibb & Sons, Inc., 5 Georges Road, New Brunswick, N.J. 08903.

This product was not reviewed by the Academy; however, the Food and Drug Administration, having evaluated data originally filed in support of efficacy of this preparation, concludes that there is a lack of substantial evidence, as defined in the Federal Food, Drug, and Cosmetic Act, that this drug is effective as a fixed combination for its claimed clinical effects, and that each component of the drug contributes to the total effects claimed for such drug.

Accordingly, the Commissioner concludes that the antibiotic drug regulations providing for certification of such drugs should be revoked.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51 as amended, 59 Stat. 463 as amended; 21 U.S.C. 352, 357) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 1481 be amended by revoking § 1481.45 *Neomycin sulfatcamphotericin B tablets.*

Interested persons may, within 30 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: October 19, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-15909 Filed 11-1-71;8:45 am]

[21 CFR Part 191]

HAZARDOUS SUBSTANCES

Proposal To Declare Certain Heavy Metal-Containing Paints and Other Surface-Coatings To Require Special Labeling for Child Protection

The heavy metals antimony, arsenic, cadmium, lead, mercury, selenium, and soluble barium may be toxic when ingested, even in small amounts. Because children may chew on interior and certain exterior residential surfaces and on toys and other children's articles, the Commissioner of Food and Drugs concludes that paints and other surface-coating materials are hazardous substances requiring special labeling warning against their use on such surfaces if they contain more of these heavy metals than is essential under good manufacturing practices, or in any event if they contain more than 0.5 percent lead; or a total of 0.05 percent of the other heavy metals listed above on a dried weight basis, except for soluble barium which shall constitute no more than 1 percent of the total barium present. The special labeling to be required shall include on the main panel a cautionary signal word "Warning", a statement of the hazard "Contains _____" (the blank being filled in with the name(s) of the applicable heavy metal(s)) and instructions to read carefully the cautionary information placed on other panel(s) where located. Existing technology will permit industry to produce household paints containing no more of these heavy metals than is specified above. As new technology becomes available, the acceptable levels may be further reduced in accordance with good manufacturing practices.

Although paints containing small amounts of lead in excess of the proposed levels may not be toxic in themselves; when considered in conjunction with other sources of lead in the environment they constitute a substantial addition to the body burden that can reasonably be avoided through the application of available technology. The Commissioner has concluded that the scope of the Federal Hazardous Substances Act fully encompasses the question of cumulative toxicity.

The American National Standards Institute, in its voluntary standard Z66.1, has specified a maximum limit since 1955 of 1 percent lead in paint intended for use on children's toys, furniture, or interior surfaces. A 1-percent lead level was also adopted by Congress in the Lead-Based Paint Poisoning Prevention Act (Public Law 91-695; 84 Stat. 2078), which is administered by the Bureau of Community Environmental Management, Health Services and Mental Health Administration. That act prohibits the use of paint with a lead content above 1 percent in residential structures constructed or rehabilitated by the Federal Government or with Federal assistance. As an additional margin of safety, the

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Commissioner proposes to reduce the exposure to lead found acceptable by Congress by establishing special labeling requirements for all household paints containing more than 0.5 percent lead.

Consideration has been given to the question of whether paints containing lead above the level specified herein should be banned from interstate commerce, or required to bear special labeling warning of the hazard involved and giving instructions for safe use. While there are numerous reports of serious injury and even death resulting from the ingestion of the dried film of old formulations of paints containing high levels of lead, the Commissioner is unaware of any similar reports as a result of ingestion of paints containing 1 percent lead or less. The Commissioner has therefore concluded that cautionary labeling will be adequate to protect the public health and safety from any potential hazards associated with the use of such paints.

Accordingly, under section 3(a) of the Federal Hazardous Substances Act, the Commissioner proposes that paints and other surface-coating materials be declared to be hazardous substances (as defined in section 2(f)(1)(A) of the Act) that require special labeling as specified herein if such paints and other surface-coating materials contain, on a dried weight basis, more than 0.5 percent lead; or a total of more than 0.05 percent antimony, arsenic, cadmium, mercury, or selenium; or soluble barium in excess of 1 percent of the total barium present. Finalization of the regulations proposed herein, in conjunction with section 2(q)(1)(A) of the Federal Hazardous Substances Act, will have the additional effect of automatically banning any toy or other article intended for use by children which is produced after effective date of these regulations and which bears such paint or other surface-coating material.

Therefore, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(B), 2(q)(1)(A), 3(a), and 3(b), 74 Stat. 372, 374-375 as amended, 80 Stat. 1304; 15 U.S.C. 1261, 1262), and the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055-56 as amended; 21 U.S.C. 371), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that a new subparagraph be added to § 191.5 (a) and that a new subparagraph be added to § 191.7(b), as follows:

§ 191.5 Products declared to be hazardous substances under section 3(a) of the act.

(a) The Commissioner finds that the following articles are hazardous substances within the meaning of the act because they are capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use:

* * * * *

(2) Paint and other surface-coating materials, produced or shipped in interstate commerce after the effective date of this regulation, containing any of the heavy metals specified below at a level exceeding that which is essential under good manufacturing practices or in any event containing amounts of such heavy metals as follows:

(i) Lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film; or

(ii) Antimony, arsenic, cadmium, mercury, and selenium of which the metal content individually or in total (calculated as the metal) exceeds 0.05 percent of the total weight of the contained solids or dried paint film; or

(iii) Barium compounds of which the water soluble barium (calculated as the metal) exceeds 1 percent of the total barium present.

§ 191.7 Products requiring special labeling under section 3(b) of the act.

* * * * *

(b) The Commissioner finds that these substances present special hazards and that the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

* * * * *

(7) Paint and other surface-coating materials declared to be hazardous under § 191.5(a)(2) shall bear on the main panel of their label, in addition to the requirements of § 191.101(a), the statement "contains _____", the blank being filled in with the name of each heavy metal present in the amount specified in § 191.5(a)(2). Such paint and other surface-coating materials shall also bear on their labeling the signal word "Warning," and the following additional statement or its practical equivalent:

"Contains _____

Dried film of this paint may be harmful if eaten or chewed.

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units, such as windowsills, porches, stairs, or railings, to which children may be commonly exposed.

Keep out of the reach of children."

the blank being filled in with the name of each heavy metal present in the amount specified in § 191.5(a)(2).

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: October 28, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-15961 Filed 11-1-71;8:52 am]

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposal To Classify Paints Containing More Than Minute Traces of Lead

The Commissioner of Food and Drugs has received a petition, submitted pursuant to section 701(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(1)(B)), proposing the issuance of a regulation under sections 2(q)(1)(B) and 3(a)(2) of the Federal Hazardous Substances Act (15 U.S.C. 1261, 1262) classifying as banned hazardous substances paint for household use containing more than minute traces of lead.

The petitioners are Joseph A. Page, Associate Professor at Georgetown University Law Center, Anthony L. Young, student, Mary Win O'Brien, student, William F. Ryan, U.S. Congressman, Jack Newfield, author, and Edmund O. Rothschild, M.D.

The petitioners propose that § 191.9(a) of the hazardous substances regulations be amended by adding thereto a new subparagraph (§ 191.9(a)(6)), as follows:

§ 191.9 Banned hazardous substances.

(a) Under the authority of section 2(q)(1)(B) of the act, the Commissioner declares as banned hazardous substances the following articles because they possess such a degree of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce:

* * * * *

(6) Paint containing lead, except for minute traces which no reasonable manufacturer could preclude from his product, as measured by the atomic absorbence method, intended for interior or exterior use, and packaged in a form suitable for use in the household as defined by § 191.1(c).

The following is the statement of grounds as presented in the petition:

STATEMENT OF THE GROUNDS UPON WHICH PETITIONERS RELY FOR THE ISSUANCE OF THE REGULATION

Human experience has established that numerous infants and young children have pica (habitual eating of nonfood substances). Human experience has also established that ingestion by children of flakes from lead based paint causes lead poisoning, the consequences of which include death, encephalopathy, neuromuscular effects, interference with the development of red blood cells, and an abnormal syndrome characterized by colic, anorexia and malaise. DHEW, PHS, Bureau of Community Environmental Management, "Control of Lead Poisoning In Children," Prepublication Draft, at I-1 (December 1970).

It is widely known that the adult system absorbs the daily intake of lead at the rate of 10 percent. Chisolm, J. Julian, "Scientific American" (February 1971). Thus, assuming the rate of absorption to be the same in

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children, a child with pica ingesting 1 gram of lead based paint (1 percent lead by ANSI standard Z66.1) daily will intake 10,000 micrograms of lead of which 1,000 micrograms will be absorbed. In addition to direct ingestion by eating flaking paint, a child will be exposed to from 14 to 269 micrograms of lead from other environmental sources. Engel, Ronald E., "Health Hazards of Environmental Lead," at Table 2 (April 1971).

It is known that blood levels of above 40 micrograms per milliliters of blood represent undue exposure to and absorption of lead. "Hearings on H.R. 17260, H.R. 13254, H.R. 14734, Before the Subcommittee on Housing of the House Committee on Banking and Currency," 91st Cong., second sess. 10 (1970). At levels of 80 micrograms per 100 milliliters a child be treated as a medical emergency. Id. While Engle in his paper has extrapolated the effect of lead fallout in children with pica, at A-9, the same must be done with 1 percent lead paint to theorize the result in children who ingest paint flakes.

In his study, Dr. Kehoe found that an adult man fed 8,000 micrograms of lead daily, in addition to the usual amount in his diet, achieved a blood lead level after 4 months of 50 micrograms lead per 100 grams whole blood. It was estimated that he would have achieved a "toxic" level of 80 micrograms lead per 100 grams whole blood if feeding had continued for 4 additional months. Kehoe, R. A., 24 "Jour. Roy. Inst. Pub. Hlth. Hyg." 81-97, 101, 129-143, 177-203 (1961). As Engle has assumed, this would be 43 micrograms per kilogram body weight in a 70 kilogram man. If a child with pica weighing 10 kilograms ingested lead to the same degree of Kehoe's subject, as Engle has suggested, then a proper assumption would be that a daily supplement of 430 micrograms lead would produce toxicity within 8 months. A child ingesting a 1 gram chip of 1 percent lead based paint would have a daily intake of almost 24 times the amount of Kehoe's subject. Obivously, intake at this rate would produce an undue medical emergency much more quickly than Kehoe foresaw for his subject.

Medical experiments cannot be performed on young children and infants to determine whether their absorption rate for lead is greater than that of adults. The child with pica must be protected from lead in his environment. The only adequate way to protect him is to eliminate the lead hazards that confront him. It is within the existing state of the art for the paint industry to eliminate lead (except for minute traces) from paint. "Hearings on H.R. 17260," supra at 246. Americans have been lulled into a feeling of security with regard to today's paints. See EPA, "Environmental Lead and Public Health," at 25 (March 1971). Many believe that lead in paint has been banned. Yet the city of New York has found paints for interior use with up to 10.8 percent lead levels on shelves of merchants within the last month. The New York Times, July 24, 1971, at 1, August 4, 1971, at 18. This despite industry's ANSI standard Z66.1 and a law banning the sale of paint for interior use with more than a 1 percent lead content without an adequate warning label.

Warning labels are, however, absolutely inadequate to prevent injury to children from lead based paints. In today's mobile society a family has no idea what their landlord or predecessor occupant has used to coat the walls of their living quarters. The generation that is suffering from lead based paint poisoning today is eating the walls of the thirties and the forties. The generation that this proposed regulation seeks to protect is yet unborn. Their parents are unborn. It would be impossible to substantiate that warning labels would have any significant impact on the future children of America. Moreover, there is no evidence that existing warning labels are efficacious for their intended purpose. The parents of the eighties and the nineties will have no opportunity to read the warning labels of the seventies.

It is not necessary to weigh the advantages of lead based paint against the health and welfare of this Nation's children and Her future children. The paint industry can produce paint without lead (except for minute traces) as measured by the atomic absorbence method. Petitioners therefore urge the Commissioner of Food and Drugs to proceed with all due speed to publish this proposal in the FEDERAL REGISTER in order that all interested persons may present their views thereon.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: October 28, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-15900 Filed 11-1-71;8:52 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 566]

[Docket No. 71-11; Notice 3]

MANUFACTURER IDENTIFICATION

Proposed Motor Vehicle Safety Regulations

The purpose of this proposed amendment to Part 566 in Title 49, Code of Federal Regulations, is to provide for the coverage of "incomplete vehicles", as defined in Part 568, Vehicles Manufactured in Two or More Stages.

A previous notice of proposed rule making published on April 28, 1971 (36 F.R. 7970), proposed a new Part 566 that would require manufacturers of motor vehicles and of motor vehicle equipment to which a motor vehicle safety standard applies to submit identifying information and a description of the items which they produce. A notice of issuance of that part is published in this issue of the FEDERAL REGISTER, 36 F.R. 20977.

In responding to a comment from an incomplete vehicle manufacturer, it was noted that while the proposed regulation clearly covers intermediate and final-stage manufacturers (as defined in Part 568) it makes no reference to incomplete vehicle manufacturers. The proposed amendment is intended to clarify this ambiguity by specifically providing for coverage of incomplete vehicles.

The incomplete vehicle manufacturer stated that he was unaware of the final use of his light truck vehicles and requested that he be permitted to submit a brief description of the incomplete vehicle expressed in the terminology of the industry as an alternative to the description in terms of final use. This proposed alternative for incomplete vehicle manufacturers has been found acceptable, and the NHTSA accordingly proposes to grant this request.

In consideration of the foregoing the NHTSA proposes that the following amendments be made to Part 566 of Title 49, Code of Federal Regulations:

1. § 566.4 would be amended to read as follows:

§ 566.4 Definitions.

All terms defined in the Act and the rules and standards issued under its authority are used as defined therein. Specifically, "incomplete vehicle", "intermediate manufacturer", and "final-stage manufacturer" are used as defined in Part 568, Vehicles Manufactured in Two or More Stages.

2. Paragraph (c)(3) of § 566.5 would be amended to read as follows:

§ 566.5 Requirements.

Each manufacturer of motor vehicles, and each manufacturer of covered equipment, shall furnish the information specified in paragraphs (a) through (c) of this section to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590.

* * * * *

(c) * * *

(3) In the case of motor vehicles produced in two or more stages, if the manufacturer is an incomplete vehicle manufacturer, the description shall so state and include a description indicating the stage of completion of the vehicle and, where known, the types of use for which the vehicle is intended.

EXAMPLE: "Chassis-cab"; "van-type truck".

If the manufacturer is an intermediate manufacturer, or a final-stage manufacturer, the description shall so state and include a brief description of the work performed.

EXAMPLE: "Multipurpose passenger vehicles: Motor homes with GVWR from 8,000 to 12,000 pounds. Final-stage manufacturer —add body to bare chassis".

Proposed effective date: February 1, 1972.

Interested persons are invited to submit comments on the proposed amendment. Comments should identify the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5221, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

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Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 502, 505, 52 Stat. 1050–53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: January 28, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-2553 Filed 2-18-72;8:46 am]

PAINTS AND OTHER SURFACE-COATINGS CONTAINING HEAVY METALS

Request for Data

In the FEDERAL REGISTER of November 2, 1971 (36 F.R. 20985), the Commissioner of Food and Drugs proposed that certain paints and other surface-coatings containing heavy metals be declared hazardous substances that require special labeling for child protection. In the same issue of the FEDERAL REGISTER (36 F.R. 20986), the Commissioner published a petition submitted by Joseph A. Page et al., proposing to classify as banned hazardous substances paints which are for household use and contain more than minute traces of lead. Interested persons were allowed 60 days to file written comments regarding these proposals.

By a letter dated February 2, 1972, petitioners requested that the Commissioner ask paint companies to submit certified analyses of their product lines "[in] order to assist in resolution of the argument of technical incapacity that the paint industry is making * * *." In consideration of this request and in view of the numerous conflicting and apparently irreconcilable comments received in response to the above proposals, the Commissioner concludes that such data would be of value in preparing the final order.

Therefore, the Commissioner hereby requests that all manufacturers of paint and/or other surface-coatings submit the following information for their interior and general purpose exterior paints and for those paints and coatings which are supplied to industry for use on toys and other children's articles as well as furniture and other household articles which may be accessible to children:

1. The total amount of each of the heavy metals lead, antimony, arsenic, barium, cadmium, mercury, and selenium (all calculated as the metal) present in the contained solids or dried paint film together with identification of the quantitative method used for such determination;

2. If barium is present, the percentage of the total barium which is water soluble barium (calculated as the metal);

3. The amount, if any, of each of the above heavy metals that was intentionally added to the product together with the reason for such addition; and

4. A current label for each analyzed product.

Products should be tested for the specified heavy metals by any generally accepted quantitative method having a sensitivity of at least 0.01 percent of the metal in the contained solids or dried paint film and a reproducibility of plus or minus 10 percent of the particular metal.

The requested data should be submitted by April 7, 1972, to the Bureau of Product Safety, 5401 Westbard Avenue, Bethesda, Maryland 20016.

Dated: February 17, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-2648 Filed 2-18-72;8:51 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. D-72-148]

AREA DIRECTORS AND DEPUTY AREA DIRECTORS

Redelegation of Authority With Respect to Requisitions for Third Party Contracts

The Assistant Secretary for Community Planning and Management is amending the redelegations of authority to Area Directors and Deputy Area Directors (35 F.R. 15408, October 2, 1970) to include under the powers set forth in section A.IV.2 the authority to approve requisitions for third party contracts.

Accordingly, the redelegations of authority published at 35 F.R. 15408 are amended to add before the period at the end of section A.IV.2 the following phrase: "* * * and third party contracts".

(Secretary's delegation of authority to the Assistant Secretary for Community Planning and Management, 36 F.R. 5004, Mar. 16, 1971)

Effective date. The effective date of this redelegation is February 22, 1972.

SAMUEL C. JACKSON,
Assistant Secretary for Community Planning and Management.

[FR Doc.72-2611 Filed 2-18-72;8:51 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGFR 72-29]

EQUIPMENT, CONSTRUCTION, AND MATERIALS

Approval Notice

1. Certain laws and regulations (46 CFR Chapter I) require that various items of lifesaving, firefighting and miscellaneous equipment, construction, and materials used on board vessels subject to Coast Guard inspection, on certain motorboats and other recreational vessels, and on the artificial islands and fixed structures on the outer Continental Shelf be of types approved by the Commandant, U.S. Coast Guard. The purpose of this document is to notify all interested persons that certain approvals have been granted as herein described during the period from December 28, 1971, to January 3, 1972 (List No. 1-72). These actions were taken in accordance with the procedures set forth in 46 CFR 2.75-1 to 2.75-50.

2. The statutory authority for equipment, construction, and material approvals is generally set forth in sections 367, 375, 390b, 416, 481, 489, 526p, and 1333 of title 46, United States Code, section 1333 of title 43, United States Code, and section 198 of title 50, United States Code. The Secretary of Transportation has delegated authority to the Commandant, U.S. Coast Guard with respect to these approvals (49 CFR 1.46(b)). The specifications prescribed by the Commandant, U.S. Coast Guard for certain types of equipment, construction, and materials are set forth in 46 CFR Parts 160 to 164.

3. The approvals listed in this document shall be in effect for a period of 5 years from the date of issuance, unless sooner canceled or suspended by proper authority.

BUOYANT VESTS, UNICELLULAR PLASTIC FOAM

NOTE: For Motorboats of Classes A, 1, or 2 Not Carrying Passengers for Hire.

Approval No. 160.052/411/0, Type I, Model AP, adult unicellular plastic foam buoyant vest manufactured in accordance with U.S.C.G. Specification Subpart 160.052, dwg. No. 052-4 dated December 27, 1971, and dwg. No. 052-1 dated December 27, 1971, manufactured by Farber Bros., 821-841 Linden Avenue, Memphis, TN 38101, effective December 28, 1971.

Approval No. 160.052/412/0, Type I, Model CPM, child medium unicellular plastic foam buoyant vest manufactured in accordance with U.S.C.G. Specification Subpart 160.052, dwg. No. 052-3 dated December 27, 1971, and dwg. No. 052-1 dated December 27, 1971, manufactured by Farber Bros., 821-841 Linden Avenue, Memphis, TN 38101, effective December 28, 1971.

Approval No. 160.052/413/0, Type I, Model CPS, child small unicellular plastic foam buoyant vest manufactured in accordance with U.S.C.G. Specification Subpart 160.052, dwg. No. 052-2 dated December 27, 1971, and dwg. No. 052-1 dated December 27, 1971, manufactured by Farber Bros., 821-841 Linden Avenue, Memphis, TN 38101, effective December 28, 1971.

HYDRAULIC AND MANUAL RELEASES FOR LIFESAVING EQUIPMENT

Approval No. 160.062/3/0, Model S-880 hydraulic and manual release for lifesaving equipment, for buoyant loads

GLD007107

N 2260.03

composition and labeling prescribed by § 27.163 for orange drink except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange Drink."

(2) The words "Containing ____ percent Orange Juice" which shall have the blank filled in with the number 10 or a number which is a multiple of 5 higher than 10 but not higher than 30 or greater than the percentage of equivalent single strength orange juice in a beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

§ 27.166 Orange flavored drink; identity; label statement of optional ingredients.

Orange flavored drink is the beverage that conforms to all of the requirements for composition and labeling prescribed by § 27.158 for orange juice drink except that:

(a) It contains less than 10 percent but more than 0 percent equivalent single strength orange juice calculated as set forth in § 27.158(d)(2) of this chapter. This requirement is considered to have been met if the content of orange juice soluble solids (exclusive of soluble solids other than orange juice soluble solids) amounts to less than 1.18 percent but more than 0 percent by weight of the finished beverage.

(b) The orange juice soluble solids requirements for orange flavored drink may be contributed solely by one or more of the orange juice ingredients described in § 27.158(b) (1) through (11).

(c) The weight of the total soluble solids is not less than 10 percent by weight of the finished beverage.

(d) The name of the beverage consists of the following two phrases which shall appear together:

(1) The words "Orange Flavored Drink" which shall be printed on a single line.

(2) The words "Containing ____ percent Orange Juice" which shall have the blank filled in with the words "less than 2" if the beverage contains less than 2 percent but more than 0 percent orange juice or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice contained in the finished beverage.

§ 27.167 Concentrate for orange flavored drink; identity; label statement of optional ingredients.

Concentrate for orange flavored drink is the beverage concentrate which, when diluted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 27.166 for orange flavored drink except that:

(a) The name of the concentrated beverage base consists of the following two phrases which shall appear together:

(1) The words "Concentrate for" which shall be on a single line immediately above the words "Orange Flavored Drink."

(2) The words "Containing ____ percent Orange Juice" which shall have the blank filled in with the words "less than 2" or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice in a beverage made by diluting the beverage concentrate as directed on the label.

(b) The dilution ratio of the beverage shall not be less than 3 plus 1. For the purpose of this section the "dilution ratio" is the whole number of volumes of water per volume of concentrate for orange flavored drink required to produce orange flavored drink conforming to the requirements for composition prescribed by § 27.166.

§ 27.168 Powdered orange flavored drink; identity; label statement of optional ingredients.

Powdered orange flavored drink is the dehydrated beverage base which when reconstituted according to label directions conforms to all of the requirements for composition and labeling as prescribed by § 27.166 for orange flavored drink except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange Flavored Drink."

(2) The words "Containing ____ percent Orange Juice" which shall have the blank filled in with the words "less than 2" or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice in a beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in six copies.

Effective date. This order shall become effective 180 days after its date of publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1040, 1055-56 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371)

Dated: March 7, 1972.

JAMES D. GRANT,
Deputy Commissioner of Food and Drugs.

[FR Doc.72-3706 Filed 3-10-72;8:45 am]

SUBCHAPTER D—HAZARDOUS SUBSTANCES

PART 191—HAZARDOUS SUBSTANCES: DEFINITIONS AND PROCEDURAL AND INTERPRETATIVE REGULATIONS

Classification of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials as Banned Hazardous Substances

In the matter of classifying certain lead-containing paints and other surface-coating materials as banned hazardous substances:

In the FEDERAL REGISTER of November 2, 1971 (36 F.R. 20985), the Commissioner of Food and Drugs published a notice proposing to declare, under section 3(a) of the Federal Hazardous Substances Act, paints and other surface-coating materials containing more than specified levels of lead and other named heavy metals to be hazardous substances (§ 191.5(a)(2)) and to be products requiring special labeling under section 3(b) of the act (§ 191.7(b)(7)). This is referred to below as the Commissioner's proposal.

In the same issue of the FEDERAL REGISTER (36 F.R. 20986), a notice was published on behalf of petitioners Joseph A. Page et al., which proposed that paint for household use containing more than minute traces of lead be classified as a banned hazardous substance pursuant to sections 2(q)(1)(B) and 3(a)(2) of the act. This is referred to below as the Page proposal.

Approximately 200 comments were received from consumers, consumer and public interest groups, the paint and chemical industries, trade associations, physicians, medical schools, professional societies, Federal, State, and local government agencies, and others. The principal comments are as follows:

The American Academy of Pediatrics, relying on published studies with lead and data respecting the maximum daily permissible intake of lead from all sources, recommended that paints containing more than 0.06 percent of lead be banned if intended for use on interior surfaces, toys, or other children's articles. The Academy agreed with the Commissioner that small amounts of lead in paints when considered in conjunction

with other sources of lead in the environment constitute a substantial addition to the body burden that can reasonably be avoided and that any unnecessary exposure should be eliminated or minimized. It also stated that the labeling of paint containers would have little effect in preventing lead poisoning and that paint containing 0.5 percent lead will not provide sufficient protection for children 1 to 3 years of age. The Academy stated that it is estimated that approximately 50 percent of these children repetitively ingest nonfood substances and that abdominal X-rays obtained in the diagnostic evaluation of children suspected of having lead poisoning indicate that very large quantities of foreign substances such as paint, putty, and plaster may be ingested, often without the parent's awareness.

The Bureau of Community Environmental Management, Health Services and Mental Health Administration, Department of Health, Education, and Welfare, commented that cautionary labeling does not provide adequate protection, that the availability of lead in paint to children should be held to the lowest concentration possible with current technology and consistent with reasonably good manufacturing practices, and that the maximum concentration of lead in paints intended for use on interior surfaces readily available to children should not exceed 0.06 percent.

The Environmental Protection Agency submitted an in-house technical report which concluded that lead in paint in excess of 0.05 percent could constitute a danger to the health of children with pica. They stated that cautionary labeling would be inadequate to protect the public health and safety and recommended that lead-based paint be banned from interstate commerce.

The medical community generally endorsed the Page proposal and supported the recommendation of the American Academy of Pediatrics. Some physicians from medical centers located in large metropolitan areas submitted the results of their own clinical findings and studies which indicate the hazard posed by lead in paint. Other physicians cited studies which indicate that children can accumulate toxic levels of lead over an extended period of time from paints containing 0.5 percent or less lead. Two physicians cited cases of children with excessive body burdens of lead which they could attribute only to paint containing less than 1 percent lead. The medical community generally commented that the labeling proposed by the Commissioner would not provide adequate protection because subsequent occupants of dwellings would not know what paints were applied by previous residents and because labeling may be totally disregarded or misinterpreted.

Nearly all comments from consumers, consumer and public interest groups, and Government agencies (other than those discussed above) endorsed the Page proposal. Some stated that the Commissioner's proposal would not provide sufficient protection against interior use of lead paints, while others suggested that lead paints for interior use be banned and that cautionary labeling be required for other lead paints. Comments from the public health departments for the cities of Philadelphia and New York state that the labeling ordinances and regulations of their cities, which are similar to those in the Commissioner's proposal, have been inadequate to protect children. Both the American Public Health Association and the health departments for the State of New York and the county of Los Angeles support the recommendation of the American Academy of Pediatrics. Some comments suggested other maximum levels for lead in paint. For example, the Congressional Black Caucus recommended that all lead from household paints be banned; the Natural Resources Defense Council and the Department of Public Health of the city of Philadelphia recommended 0.05 percent as a maximum level for lead in paint.

Paint chemical manufacturers and their trade associations generally supported the Commissioner's proposal and opposed the Page proposal. With respect to the Commissioner's proposal, several comments requested clarification of the labeling statement and sufficient time to reformulate and relabel their products. With respect to the Page proposal, many comments stated that the language "minute traces of lead" is vague and nonspecific; that the data relied on by the petitioners and by the American Academy of Pediatrics is based on lead ingestion studies done with lead compounds other than the lead compounds used in paints and coatings; that scientific data or human experience has not proven that paints containing 1 percent lead are hazardous; that lead is used as a dryer and the substitution of other compounds for lead may be hazardous; and that implementation would cause a severe economic hardship because it is not within the existing state-of-the-art of the paint industry to eliminate all lead from all paint. Several comments contended that the statutory procedures for banning have been ignored in the Page proposal in that only after labeling has been proven inadequate can consideration be given to banning. Other comments stated that warning labels are adequate protection because they prevent misapplication of paint products and serve the public interest by allowing useful, needed paint products to remain on the market. Some comments stated that lead is a necessary component of certain products (e.g., certain exterior primers, rust inhibitors, and automobile touchup paint).

A number of paint manufacturers and their trade associations commented that the inclusion of heavy metals other than lead in the Commissioner's proposal is inappropriate. They stated that the toxicity of different forms of these metals has not been established and suggest that action be deferred pending further scientific investigation. Some manufacturers submitted data which they contend shows that certain heavy metal compounds other than lead are not hazardous, while others stated that adequate test methods need to be developed. Another manufacturer stated that certain of these heavy metals are necessary in the manufacture of fire-retardant coatings and warning colors. Only a few other comments were received that expressed an opinion concerning the Commissioner's proposal as it related to other heavy metals, and none of these were supported by scientific data.

The Commissioner, having considered the comments and other relevant material, concludes as follows:

Although paints and other surface-coating materials containing lead do not present an imminent hazard to the public health, they must be considered on the basis of cumulative toxicity over extended periods of time and in conjunction with other sources of lead in the environment. Based on the currently available scientific and medical data, regulatory action must be taken to minimize the health hazard to future generations.

The health hazard from lead will not be effectively eliminated by cautionary labeling requirements. The statute does not provide that such labeling must be tried and proven inadequate before a hazardous substance can be banned. Instead, section 2(q)(1)(B) explicitly provides for banning products from interstate commerce on the basis of a specific finding "notwithstanding such cautionary labeling as is or may be required." Cautionary labeling has not been proven effective in eliminating lead poisoning in many cities which presently have such requirements. In any event, the hazard persists long after the product has been separated from its labeling.

The prudent course of action is to reduce, as rapidly as possible, the amount of lead to which children are exposed. The Commissioner agrees that limiting the amount of lead to "minute traces," as set forth in the Page proposal, is not feasible because that phrase is vague and would not provide manufacturers with specific standards, and it could not be effectively enforced by the Food and Drug Administration. In addition, limiting regulatory action only to paint is inadequate to protect the public health and safety because other surface-coating materials containing lead are used in and around the household and are accessible to children.

The preponderance of medical opinion supports a regulation limiting the amount of lead in products intended for interior surfaces and for toys or other children's articles to 0.06 percent because that level will provide a margin of safety. However, such a regulation would not prevent the use of products containing higher amounts of lead on exterior surfaces. These surfaces are generally as accessible to children as interior surfaces, and, as the comments points out, children have been subjected to lead poisoning by ingesting products containing lead that were applied to exterior surfaces. In addition, if products containing lead are available for exterior use, they may be misused for interior surfaces.

The Commissioner recognizes that restrictions placed upon the use of lead may result in economic hardship and in the substitution of other components for use as dryers. The statute makes no exception for economic hardship. Several compounds have been suggested as substitutes for lead. Each manufacturer, prior to marketing consumer products, must take steps to determine that any substitute for lead has been adequately tested for safety and shown to be safe. Any banning order should therefore provide a reasonable time to test substitutes for lead and establish their safety, and at the same time provide adequate protection to the public.

Th National Paint and Coatings Association, which represents more than 000 companies, has notified the Commissioner that it anticipates its members can produce by January 1974 interior products not exceeding the 0.06 percent maximum lead level and can produce by January 1975 exterior products not exceeding the 0.06 percent maximum lead level. Some paint and chemical manufacturers have notified the Commissioner that they can reformulate their products to meet the 0.06 percent maximum lead level in a shorter time period. On February 19, 1972, a notice was published in the FEDERAL REGISTER (37 F.R. 3780) requesting that additional information from the industry be submitted by April 7, 1972. If, after considering this information, the Commissioner finds that lead can be eliminated from paints and other surface-coating materials more rapidly than the implementation dates specified in the following order, an appropriate amendment will be made.

Therefore, the Commissioner finds that, notwithstanding such cautionary labeling as is or may be required under the Federal Hazardous Substances Act, the degree or nature of the hazard involved in the presence or use of lead in paints and other surface-coating materials in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substances, when so intended or packaged, out of the channels of interstate commerce. Under section 2(q)(1) of the act, this will have the additional effect of banning such products from use on any toy or other article intended for use by children.

Since lead may be a necessary component of products intended for particular uses, as suggested by several comments, the Commissioner is prepared to consider petitions propposing amendment of the regulation. Pursuant to 21 CFR 191.201, petitions showing reasonable grounds will be published in the FEDERAL REGISTER. Consideration will also be given in late 1973 to petitions for extension of the implementation date upon a showing that the public health will not be jeopardized and that technological necessity requires additional time to meet the 0.06 percent maximum lead level.

At this time, further information is required before a final order can be promulgated regarding the use of certain elements, other than lead, in paint and other surface-coating materials. Additional data on the use of these materials will be obtained in response to the FEDERAL REGISTER notice of February 19, 1972 (37 F.R. 3780), and these products will be considered at a later date.

Therefore, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2 (f)(1)(A), (q); 74 Stat. 372, as amended, 80 Stat. 1304-05; 15 U.S.C. 1261 (f)(1)(A), (q)) and the Federal Food, Drug, and Cosmetic Act (sec. 701 (e), (f), (g); 52 Stat. 1055-56 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 371 (e), (f), (g)), and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That Part 191 be amended by adding a new subparagraph (6) to § 191.9(a), as follows:

§ 191.9 Banned hazardous substances.

(a) Under the authority of section 2(q)(1)(B) of the act, the Commissioner declares as banned hazardous substances the following articles because they possess such a degree of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce:

* * * * *

(6) (i) Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household that:

(*a*) Is shipped in interstate commerce after December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(*b*) Is shipped in interstate commerce between December 31, 1972, and December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(ii) Any toy or other article intended for use by children that:

(*a*) Is shipped in interstate commerce after December 31, 1973, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(*b*) Is shipped in interstate commerce between December 31, 1972, and December 31, 1973, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Maryland 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in six copies. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective 45 days after its date of publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 2 (f)(1)(A), (q), 74 Stat. 372, as amended 80 Stat. 1304-05, 15 U.S.C. 1261(f)(1)(A), (q); sec. 701 (e), (f), (g), 52 Stat. 1055-56 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 371 (e), (f), (g))

Dated: March 8, 1972.

JAMES D. GRANT,
Deputy Commissioner of Food and Drugs.

[FR Doc.72-3760 Filed 3-10-72;12:30 p.m.]

Title 26—INTERNAL REVENUE

[T.D. 7167]

Chapter I—Internal Revenue Service, Department of the Treasury

SUBCHAPTER A—INCOME TAX

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Rehabilitation of Low-Income Housing

On August 4, 1970, notice of proposed rule making with respect to the amendment of the Income Tax Regulations (26 CFR Part 1) to conform the regulations to the provisions of section 521(a) of the Tax Reform Act of 1969 (83 Stat. 651), relating to rehabilitation of low-income housing, was published in the FEDERAL REGISTER (35 F.R. 12400). After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the amendment as proposed is hereby adopted, subject to the changes which follow: Sections 1.167(k)-1 through 1.167(k)-4 are revised to read as set forth below.

(Sec. 167(k), Internal Revenue Code of 1954, 83 Stat. 651; 26 U.S.C. 167; sec. 7805, Internal Revenue Code of 1954, 68A Stat. 917; 26 U.S.C. 7805)

[SEAL] JOHNNIE M. WALTERS,
Commissioner of Internal Revenue.

Approved: March 2, 1972.

FREDERIC W. HICKMAN,
Acting Assistant Secretary of the Treasury.

16078

(i) Results of tests and assays on:

(a) The griseofulvin used in making the batch for potency, safety, loss on drying, melting point, specific rotation, identity, residue on ignition, heavy metals, specific surface area, and crystallinity.

(b) The batch for potency and pH.

(ii) Samples required:

(a) The griseofulvin used in making the batch: 10 packages, each containing not less than 1 gram.

(b) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Spectrophotometric assay.* Proceed as directed in § 148g.1(b)(1)(i), except prepare the sample for assay as follows: Prepare a 0.50 milligram per milliliter solution (estimated) of the suspension by transferring an appropriate volume of the well-shaken suspension to a 100-milliliter volumetric flask. Add about 50 milliliters of methyl alcohol to the flask. Warm the contents by heating the flask carefully over a steam bath. Swirl the contents several times during the heating period. Shake the flask on a mechanical shaker for 15 minutes, allow to cool to room temperature, and adjust to volume with methyl alcohol. Mix well. Filter the solution, discarding the first 10 to 15 milliliters of filtrate. Transfer exactly 1.0 milliliter of the subsequent filtrate to a 50-milliliter volumetric flask, adjust to volume with methyl alcohol, and mix well. Using a suitable ultraviolet spectrophotometer and matched 1 centimeter quartz cells, set the instrument to 100 percent transmission with methyl alcohol. Determine the absorbance of the sample and working standard (prepared as described in § 148g.1(b)(1)(i)(a)) at the absorption peak at 292±2 nanometers. Calculate the milligrams of griseofulvin per milliliter of sample as follows:

$$\text{Milligrams of griseofulvin per milliliter} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times \frac{\text{Weight of standard in milligrams}}{\text{Milliliters of suspension tested}} \times \frac{\text{Potency of standard in micrograms per milligram}}{1,000}$$

(ii) *Microbiological agar diffusion assay.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured volume of the well-shaken suspension with sufficient dimethylformamide to give a stock solution containing 100 micrograms of griseofulvin per milliliter (estimated). Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 5.0 micrograms of griseofulvin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 141.503 of this subchapter, using the undiluted suspension.

Data supplied by the manufacturer concerning the safety and efficacy of the subject antibiotic drug have been evaluated. Since the conditions prerequisite to providing for certification of this drug have been complied with and since the matter is not controversial, notice and public procedure and delayed effective date are not prerequisites to this promulgation.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (8–10–72).

(Sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357)

Dated: August 2, 1972.

H. E. SIMMONS,
Director, Bureau of Drugs.

[FR Doc.72-12501 Filed 8-9-72;8:46 am]

SUBCHAPTER E—HAZARDOUS SUBSTANCES

[Docket No. FDC HS-2]

PART 191—HAZARDOUS SUBSTANCES: DEFINITIONS AND PROCEDURAL AND INTERPRETATIVE REGULATIONS

Certain Lead-Containing Paints and Other Similar Surface-Coating Materials as Banned Hazardous Substances; Confirmation in Part of Effective Date of Order

In the matter of classifying certain lead-containing paints and other surface-coating materials as banned hazardous substances (21 CFR 191.9(a)(6)) within the meaning of section 2(q)(1) of the Federal Hazardous Substances Act:

In the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5229), the Commissioner of Food and Drugs published an order under section 2(q)(1)(B) of the said act declaring paint and other similar surface-coating materials for use in or around the household to be a banned hazardous substance if shipped in interstate commerce after December 31, 1972, containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or the dried film. Separate provisions of that order also banned shipment in interstate commerce after December 31, 1973, of paint and other similar surface-coating materials for use in or around the household that contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or the dried film. Finally, the order specifically provided, as required by section 2(q)(1)(A) of the act, that any toy or other article intended for use by children bearing such paint and other similar surface-coating materials after those respective dates would also be a banned hazardous substance.

Pursuant to section 2(q)(2) of said act and section 701(e) of the Federal Food, Drugs, and Cosmetic Act, 30 days were provided for filing written objections and requests for hearings.

Twenty-five timely submissions were received with respect to this order. Although some of these submissions related to the 0.5 percent lead level to be implemented as of December 31, 1972, the majority of the submissions were concerned with the 0.06 percent lead level to be implemented December 31, 1973. The Commissioner finds that these two different levels and effective dates present separate and distinct issues that require separate consideration. Accordingly, this document rules only upon the submissions made with respect to the 0.5 percent lead level to be implemented as of December 31, 1972. A future document will rule upon the submissions with respect to the 0.06 percent lead level to be implemented as of December 31, 1973.

The majority of the submissions endorsed the 0.5 percent lead level to be implemented as of December 31, 1972. The National Paint and Coatings Association previously endorsed this level in a letter to the Commissioner dated February 2, 1972, and the submission of the New York Paint, Varnish, and Lacquer Association and the submission of the Federation of Societies for Paint Technology supported this provision.

McCloskey Varnish Co. objected to the 0.5 percent lead level but failed to submit supporting grounds and in any event did not request a public hearing on their objections. Other submissions protested the 0.5 percent level but did not submit formal objections or request a public hearing. Precision Paint Corp. requested an additional 6 months to comply with the 0.5 percent level but did not submit formal objections or request a public hearing.

The National Decorating Products Association and Benjamin Moore & Co. submitted objections and a request for a public hearing with respect to the 0.5 percent lead level on the ground that the time for compliance should be extended 18 months for retailers and distributors. The National Retail Hardware Association submitted an objection on this issue but did not request a public hearing. Two other submissions objected on the ground that the 0.5 percent lead level offers no relief since those products would be banned and subject to repurchase when the 0.06 percent lead level

becomes effective, but no public hearing was requested on that issue.

The Commissioner has evaluated the objection and request for public hearing by the National Decorating Products Association and Benjamin Moore & Co. and concludes that they are not supported by grounds legally sufficient to justify the relief sought. Neither submission contended that the lead content of paint should not be reduced to 0.5 percent to reduce the health hazard to children. Both submissions contended only that retailers and distributors should have an additional 18 months to dispose of existing inventories. No information was submitted to show that it will take an additional 18 months to dispose of existing inventories, or that such an extension of time would not be utilized to overstock noncomplying paint in order to avoid the regulation. The act contains no provision authorizing the Commissioner to grant an exemption for retailers and distributors to sell existing inventories that fail to conform to applicable regulations, and indeed any such provision would clearly violate the law. Retailers and distributors have known since March 11, 1972, that further interstate shipment of household paint containing more than 0.5 percent of lead would be unlawful, and have therefore had sufficient opportunity to eliminate nonconforming paint from their inventory. Submissions to the Commissioner in response to his request published in the FEDERAL REGISTER of February 19, 1972 (37 F.R. 3780), with respect to the present lead content of paint, demonstrate that there is already a sufficient supply of household paint meeting the 0.5 percent lead level to satisfy all existing needs. Accordingly, since the act does not provide for an extension of time for retailers and distributors to sell existing inventories, the Commissioner concludes that the objections submitted by the National Decorating Products Association and Benjamin Moore & Co. are legally insufficient to justify a public hearing on this matter. The Commissioner therefore denies this request for a public hearing.

Borden, Inc., objected to the 0.5 percent lead level on the ground that there is no substantial evidence that adequate cautionary labeling cannot be written. This submission did not contend that the lead content of paint used in or around a household should not be reduced to 0.5 percent to reduce the health hazard to children. Since the submission presented no basis whatever to show that cautionary labeling will prevent the use of lead-based paint in or around a household (for example, particularly a household where children presently do not live), and since there is obviously no way to require cautionary labeling on walls painted with lead-based paint so that future occupants will be aware of the potential hazard, the Commissioner concludes that this objection is not supported by grounds legally sufficient to justify a public hearing on the issue. In any event, the Borden submission states that, if no hearing is granted to any other party regarding the matter, the request for a public hearing is withdrawn. Accordingly, since no other party requested a public hearing on any issue that is being granted, the Commissioner concludes that a public hearing will not be held on the matter.

Professor Joseph A. Page et al. of the Georgetown University Law Center objected to the 0.5 percent lead level insofar as it disregards the repurchase provisions of section 15 of the act and insofar as it permits an additional year to meet the 0.06 percent lead level. Since section 15 of the act applies to all banned hazardous substances and is in any event not enforceable by the Commissioner under the act, it would be inappropriate to make any provision with respect to repurchase in this or any other regulation relating to a banned hazardous substance. The act also explicitly permits the Commissioner to establish appropriate implementation dates. The Commissioner concludes that the objections are not supported by grounds legally sufficient to justify a public hearing, and in any event the Page submission states that no public hearing is requested on these matters.

Two submissions were made after the statutory time for objections had expired. One of these, submitted by American Home Products Corp., objected generally to the order as not providing adequate support for the severity of the limitations established and requested a hearing to resolve the legal issues raised by the absence of supporting data for the order. Since the American Home Products Corp submission failed to specify with particularity the provisions of the order deemed objectionable and the grounds for the objections, requested a hearing to resolve legal issues, and failed to state a factual basis sufficient to justify a public hearing, and in view of the fact that the submission was not made within the statutory time period, the Commissioner concludes that this submission does not require a public hearing.

The order promulgating § 191.9(a)(6) in the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5229), stated that it would become effective 45 days thereafter unless stayed by the filing of proper objections. This effective date is not to be confused with the implementation dates contained in the regulations.

In view of the above findings, the Commissioner concludes that those portions of § 191.9(a)(6) pertaining to the 0.5 percent lead level should be confirmed as effective. Those portions pertaining to the 0.06 percent lead level will be the subject of a separate document to be published at a later date.

Therefore, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(A), (q), 74 Stat. 372, 374, as amended 80 Stat. 1304-1305; 15 U.S.C. 1261(f)(1)(A), (q)) and the Federal Food, Drug, and Cosmetic Act (sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 371 (e), (f), (g)), and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That the effective date of all but subdivisions (i)(a) and (ii)(a) of § 191.9(a)(6) became effective April 25, 1972, and that a document ruling upon subdivisions (i)(a) and (ii)(a) will be published at a later time.

Dated: August 4, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-12502 Filed 8-9-72;8:46 am]

Title 43—PUBLIC LANDS: INTERIOR

Subtitle A—Office of the Secretary of the Interior

PART 19—WILDERNESS PRESERVATION

Hearing Procedures

43 CFR Part 19 was contained in Circular 2203, 31 F.R. 3011, February 22, 1966.

Paragraph 19.5(a) is amended as follows: In the third sentence of § 19.5(a) substitute the figure "30" for the figure "60".

Because this amendment relates to internal wilderness area administrative procedures, notice and public procedure thereon is deemed unnecessary, and this amendment will become effective upon publication in the FEDERAL REGISTER (8-10-72).

HARRISON LOESCH,
Assistant Secretary of the Interior.

AUGUST 4, 1972.

[FR Doc.72-12523 Filed 8-9-72;8:48 am]

Chapter II—Bureau of Land Management, Department of the Interior

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5244]

[Nevada 6029]

NEVADA

Withdrawal of Lands for Air Navigation Site

By virtue of the authority contained in section 4 of the Act of May 24, 1928, 49 U.S.C. section 214 (1970), it is ordered as follows:

1. Subject to valid existing rights, the following described public land, which is under the jurisdiction of the Secretary of the Interior, is hereby withdrawn from all forms of appropriation under the public land laws, including the mining laws, 30 U.S.C. Ch. 2, but not from leasing under the mineral leasing laws, and reserved for use by the Federal Aviation Administration, Department of Transportation, as an air navigation site:

MOUNT DIABLO MERIDIAN

T. 4 N., R. 68 E.,
Sec. 6: lot 1.

(a) Amounts deposited pursuant to subdivisions (i), (ii), and (iii) of this subparagraph (including any voluntary deposits made pursuant to paragraph (b) (3) of this section), and

(b) Amounts paid pursuant to paragraph (a) (1) of § 1.1461-3, for such calendar year,

the withholding agent shall deposit the balance of tax due for such year with a Federal Reserve bank or authorized commercial bank on or before the 15th day of the third month following the close of the calendar year.

(v) *Transitional rules.* Notwithstanding the provisions of paragraph (a) (1) of § 1.1461-3 and of subdivisions (i) and (ii) of this subparagraph, the aggregate amount of tax required to be withheld under chapter 3 of the Code by any withholding agent after December 31, 1966, and before June 1, 1967, shall be deposited with a Federal Reserve bank on or before June 22, 1967. For the purpose of paragraph (b) (2) of this section any amount deposited in accordance with the requirement of this subparagraph shall be considered as if it were deposited with respect to amounts withheld during the calendar quarter beginning April 1, 1967.

(3) *Cross reference.* For rules relating to the adjustment of deposits, see § 1.1461-4(b) and § 1.6414-1. For rules requiring payment of any undeposited tax, see § 1.1461-3.

* * * * *

[FR Doc.72-20913 Filed 12-4-72;8:53 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 905]

ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Proposed Handling Limitations

Consideration is being given to the following proposal submitted by the committees, established under the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The proposal would extend current grade and size limitations, for the period January 1, 1973, through September 30, 1973, applicable to oranges, including Navel, Temple, and Murcott Honey oranges (but not including Valencia, Lue Gim Gong, and similar late maturing oranges of the Valencia type), handled between the production area and any point outside thereof in the continental United States, Canada, or Mexico.

The proposed extension of the period of regulation of certain varieties of oranges is designed to continue in effect the current quality and size requirements for such fruits consistent with (1) the available supply and the demand for such fruits; and (2) improving returns to producers pursuant to the declared policy of the act.

The proposal is as follows:

Order. In § 905.545 (Orange Regulation 71; 37 F.R. 21799, 24432, 25036) the provisions of paragraph (a) preceding subparagraph (1) thereof are amended to read as follows:

§ 905.545 Orange Regulation 71.

(a) During the period January 1, 1973, through September 30, 1973, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico.

* * * * *

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposal shall file the same, in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than the 10th day after publication of the notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: November 30, 1972.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.72-20826 Filed 12-4-72;8:48 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposed Exemption of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials

The Commissioner of Food and Drugs has received a petition from the National Paint and Coating Association, 1500 Rhode Island Avenue NW., Washington, DC 20005, submitted pursuant to section 701(e) (1) (B) of the Federal Food, Drug, and Cosmetic Act, proposing an amendment to a regulation (21 CFR 191.9(a) (6) (i)) promulgated under section 2(q) (1) (B) of the Federal Hazardous Substances Act. The proposed amendment would exempt certain lead-containing coatings from classification as banned hazardous substances.

The petition states that the submission is on behalf of its members which manufacture and market certain specialty paints in which lead is a necessary component.

Section 191.9(a) (6) was promulgated in the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5229), and its effective date was confirmed in part in the FEDERAL REGISTER of August 10, 1972 (37 F.R. 16078).

The proposed amendment prepared by the petitioner reads as follows:

§ 191.9 Banned hazardous substances.

(a) * * *

(6) (i) * * *

(c) The provisions of this subdivision (i) do not apply to:

(1) Automotive, agricultural, and industrial equipment refinish coatings;

(2) Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings;

(3) Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses and for identification marking in industrial buildings);

(4) Touchup coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances;

(5) Exterior marine coatings for small craft application;

(6) Exterior rubber-based roof coatings; and

(7) Exterior primer coatings for wood siding containing extractives (products marketed solely for application on redwood and cedar);

Provided, That these products bear on the main panel of their label, in addition to any labeling that may be required under the act or regulations promulgated pursuant thereto, the signal word "WARNING" and the following statement: "CONTAINS LEAD. DRIED FILM ON THIS PAINT MAY BE HARMFUL IF EATEN OR CHEWED. See other cautions on (side or back) panel." These products shall also bear on their label the following additional statement or its practical equivalent:

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units, such as window sills, porches, stairs, or railings, to which children may be commonly exposed.

Keep out of reach of children.

The placement, conspicuousness, and contrast of the above labeling shall be in accordance with the requirements of § 191.101.

* * * * *

The following is the statement of grounds given in the petition in support of the proposed amendment:

On March 11, 1972, the Food and Drug Administration published an order in the FEDERAL REGISTER (37 F.R. 5229) under section 2(q) (1) (B) of the Federal Hazardous Substances Act which, in part, declared any paints or other similar surface-coating materials intended, or packaged in a form suitable for use in or around the household, to be banned hazardous substances if: (1) Shipped in interstate commerce between December 31, 1972, and December 31, 1973, and (2) containing lead compounds of which the lead content is in excess of 0.5 percent of the total weight of the contained solids or dried paint film. On August 10, 1972, this portion of the order was confirmed as effective; that portion of the order pertaining to a 0.06 percent lead level remained under consideration by the Agency.

The Federal Hazardous Substances Act applies to paint products which are found to be toxic, which are intended or packaged in a form suitable for use in or around a household, and which may cause substantial personal injury or illness as a result of "reasonably foreseeable ingestion by children" (15 U.S.C. 1261(f)(1)(A)). Most paints in liquid form are not considered toxic under this act because the viscosity of the paint product renders the ingestion hazard extremely remote. Only after the paint product has been applied to a surface accessible to children, and then usually only after the film has flaked or chipped, does a hazard arise that children may ingest the lead content.

Thus, this petition is not necessary because of the requirements of the act since the specialty paints, which are the subject of this petition, are neither intended nor likely to be used on surfaces which are reasonably available to children or on surfaces which will enable flaking and chipping of the paint. This petition is required only because the language of § 191.9(a)(6)(i) appears to be broader in scope than the language in the statute and broader in scope than is necessary to protect against the lead hazard from the dried paint film. The pertinent portion of the regulation reads as follows: "Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household". If this operative language had been limited to surface-coating materials which after application would pose a lead hazard because of reasonably foreseeable ingestion by children, it is clear that the regulation would not apply to these specialty products. This petition for an amendment is submitted, therefore, only to clarify the scope of § 191.9(a)(6)(i) of the regulations.

The Definitions and Procedural and Interpretative Regulations, under FHSA (21 CFR Part 191.1), specify that the act covers those products that under customary or reasonably foreseeable conditions of storage or use may be brought into or around a house, apartment, or other place people dwell, including a garage, carport, barn, or storage shed. The same regulations expressly state that the act does not cover industrial supplies that might be taken into a home by a serviceman. The interpretations specifically provide that a product labeled as and marketed solely for industrial use does not become subject to the act simply because an industrial worker could possibly misappropriate a supply for his own use.

Thus, this interpretative regulation leaves no doubt that industrial coatings, such as original finish coatings for automobiles, industrial equipment, and farm and garden equipment are outside the scope of the act and therefore remain unaffected by the proposed tolerances. The specialized coating products which are the subject of this petition are similar to the industrial or factory-applied coatings in many respects. They are intended primarily for application to nonhousehold surfaces, usually by professional painters, and they are not intended or suitable for use on surfaces accessible to children which would create a hazard. The March 11 regulation appears to cover these specialized paints solely because they may at times be found in or around the household in packaged form and not because of any finding that they pose a lead hazard to children.

Congress, in enacting the Federal Hazardous Substances Act, contemplated the dangers offered by a product or article in its liquid state and in its packaged form and thus designed the act to regulate all products "intended or packaged in a form suitable for use in or around the household." Implicit in the quoted language is the assumption that the particular hazard from a product is posed simply because that product is present in the household in packaged form. While this is true of a substance which presents a hazard in its liquid state as, for example, the flammability hazard of certain liquid paints, this is not true of the lead ingestion hazard from paints. The particular hazard posed by lead content in paint does not occur from the liquid paint in the package but, instead, the hazard occurs solely from the dried paint film if ingested by children.

The best information available indicates that children who are disposed to chew paint chips confine their activity primarily to interior surfaces in the house and, perhaps, infrequently to an accessible exterior surface. Children usually are attracted by flakes from old, chipped paint film rather than newly-coated surfaces, and by toys or other articles which they may place in their mouths. This is due in large part to the limited physical abilities of the young children suffering from "pica," the habit of ingesting nonfood items.

As pointed out in comments to the subject regulation, submitted by Dr. Barry King and Dr. Julian Chisholm (noted authorities on lead poisoning), the most critical age for exposure of a child through ingestion of paint, putty, and other lead-containing nonfood materials is usually 1 to 3 years of age. In view of both the restricted mobility and physical limitations of children in this age bracket, they neither have access to, nor are capable of chewing or ingesting, paint chips from surface to which the products for which exemptions are herein requested are applied. In fact, we are not aware of any documented case where a child has attempted to ingest the paint film on automobiles, farm and garden implements, etc.

The American Academy of Pediatrics, in its November 30, 1971 memorandum to the Food and Drug Administration, appears to confirm this: "The American Academy of Pediatrics endorses the principle contained in the petition filed with the Commissioner that paints containing more than minute traces of lead be declared as banned hazardous substances, if intended for use on children's products or interior surfaces (emphasis supplied)." Further, the Senate Committee Report on the Lead-Based Paint Poisoning Prevention Act Amendments of 1972 refers specifically to coatings "intended for interior residential surfaces" (S. Rep. No. 92-852, 92d Cong., 2d Sess. (1972)).

Similarly, under the Lead-Based Paint Poisoning Prevention Act (Public Law 91-695) the Secretary of Housing and Urban Development, in consultation with the Secretary of Health, Education, and Welfare, was instructed to develop and carry out a demonstration and research program "to determine the nature and extent of the problem of lead-based paint poisoning in the United States, particularly in urban areas, and the methods by which lead-based paint can most effectively be removed from interior surfaces, porches, and exterior surfaces to which children may be commonly exposed, of residential housing."

Acting under this authority, the Secretary of HUD has determined that the existing conditions that pose a lead paint hazard to children are those surfaces reasonably available to children that present peeling or flaking paint. This has been recently confirmed by the agency by a publication in the October 21, 1972, issue of the FEDERAL REGISTER (at page 22732) entitled "Prohibition of Use of Lead-Based Paint and Elimination of Lead-Based Paint Hazard." This revises pertinent parts of the Code of Federal Regulations already promulgated under authority of the Lead-Based Paint Poisoning Prevention Act. In this revision, with respect to the use of and elimination of existing hazards caused by lead-based paint, the Secretary of HUD defines "applicable surfaces" as all interior surfaces and those exterior surfaces, such as stairs, decks, porches, railings, windows, and doors, which are readily accessible to children under 7 years of age." Further, "Health Hazard," with respect to lead-based paint, is defined to mean "crackling (sic), scaling, peeling, and loose lead-based paint on applicable surfaces."

Since the prohibition against use of lead-based paint under this revision extends only to use on "applicable surfaces of any residential structure," clearly then these are the only surfaces found by this agency to pose a lead hazard to children. There is no indication by HUD that the surfaces to which the products under consideration are applied present either an existing or future lead poisoning hazard to children.

It is clear from the foregoing that the hazard sought to be prevented by lead tolerances established in § 191.9(a)(6) is lead ingestion by children who tend to chew dried paint film on interior and exterior household surfaces accessible to these children, and on toys or other articles intended for use by these children. The regulation is not intended to nor should it reasonably apply to the specialized paints under consideration since, through customary or reasonably foreseeable conditions of use, they will not cause a lead hazard for pica children, even though they are packaged in a form suitable for use in or around the household, and thus, incidentally may meet

the definitional test of § 191.1(c), namely, that "under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling." Thus, petitioners believe these products should not be subject to the provisions of the regulation.

Unlike interior household paints or even exterior paints for household application which could conceivably be substituted for interior use or applied on an exterior surface accessible to children, these specialized products are never marketed for such application. They are neither intended, designed, nor suitable for use in areas accessible to children. These products are limited in purpose and, since they are not general household products, are thus purchased infrequently and never stored around the household in any significant quantity. Furthermore, most of these products are intended for the professional consumer.

The precautionary label proposed in this petition adds an extra measure of protection against any conceivable risk from its lead content due to misuse. The possibility of misusing these products, even without the precautionary label is, however, very remote. The garish color and rough texture of an industrial maintenance coating, such as a red-lead primer in which lead is an important protection material, makes it exceedingly unlikely that anyone would use it on interior household surfaces or other surfaces accessible to children. Other specialty products, such as automobile refinishes, are generally too expensive to be feasible for use on such surfaces. Others, such as touchup coatings in aerosol containers, are packaged in quantities too small for practical use on household surfaces. Additional significant factors militating against misuse of these products are explained in the following discussions of the individual products along with an explanation of why lead is a necessary component in these coatings.

DISCUSSION OF SPECIAL PURPOSE COATINGS

1. *Automotive, agricultural, and industrial equipment refinish coatings.* Automotive, agricultural, and industrial equipment refinish coatings are designed for use by automobile repair shops or agricultural or industrial equipment dealers for the refinish of automobiles, trucks, agricultural, and industrial machinery. These refinish coatings are marketed through automotive warehouse distributors to automotive parts jobbers, and then to automotive body shops. Agricultural and industrial equipment coatings are sold by equipment manufacturers and subsidiaries to equipment dealers.

Although these refinish coatings are intended for use by automotive body shops or farm and industrial equipment dealers and are not marketed primarily for retail customers, some of these companies have a secondary retail trade. Such retail customers use these coatings to refinish automobiles, agricultural equipment, and industrial machinery. This refinishing may occur in or about a garage, barn, or shed.

These coatings are usually high-gloss and are customarily applied by spray equipment. Lead is an essential ingredient in many of these coatings for three reasons. First, it is a catalytic drier, necessary to speed the oxidation process and, thereby, prevent dirt or dust from becoming embedded in the film. Second, lead-containing pigments are necessary to match original equipment colors and to prevent a displeasing patchwork effect in coloring which otherwise would appear after a short time due to color chalking and fading. Finally, lead provides the essential resistance to weathering, heat, and other environmental conditions to which automobiles, agricultural and industrial equipment are peculiarly exposed.

When used for the intended purpose, there exists no health hazard to children. Indeed, the only difference between the original factory-applied finish (which is not regulated by the act unless applied to any toy or other articles intended for use by children) and the refinish product is that a can of the latter may find its way into or near the home. The hazard exists, however, not from the liquid in the container but only from the dried film and then only if the film can be ingested by children. It is not reasonably foreseeable that a child would chew on the paint because of the hard substrate to which the paint is applied.

Because of the nature of these refinishing products and their labeling, it is not reasonably foreseeable that they would be used for other than their intended purpose. There are many reasons for this:

a. Spray application, usually with high-pressure sprayers, is recommended for all of these products, and satisfactory results are not obtained with a brush or roller;

b. The high gloss colors found in most of these coatings are not suitable for surfaces in the home;

c. At the retail level, automotive refinishes are roughly twice as expensive as household enamels and paints, and thus it is exceedingly unlikely that consumers would purchase automotive refinish coatings for use on either an interior or exterior household surface since cheaper, better-suited products are more readily available. Further, such costs preclude purchasing more than is actually needed to refinish an automobile;

d. These refinishes, in contrast to general purpose household enamels and paints, often require careful preparation of the metal surface, including grinding, etching, and priming in order to obtain proper adhesion; and

e. The proposed warning label would provide additional protection by indicating to the purchaser that such coatings should not be applied on any surface accessible to children.

2. *Industrial (and commercial building) maintenance coatings, including traffic and safety markings coatings.* This category includes a variety of coatings sold for maintenance of plant and equipment, commercial buildings, structural steel (such as bridges), or for safety markings or pavement markings in streets or parking lots. Lead pigment, such as in the commonly used red-lead primer, is an important ingredient in these coatings, principally because it resists corrosion. Lead pigments also achieve the brilliant opaque and durable colors required for safety markings on pavements and industrial areas. There are no substitutes for the lead colors that will adequately perform the same purposes. Organic compounds are weaker in tinting strength, are less durable to weathering, and have a tendency to bleed when overpainted.

Those products are intended for uses which pose no health hazard of children. Industrial plants, commercial office buildings, metal equipment, structural steel, bridges, and the like are not accessible to children. Additionally, the Congress, after hearings, has recognized that such uses are not hazardous. In enacting the Lead-Based Paint Poisoning Prevention Act of 1971 (Public Law 91-695), Congress eliminated the language "any building or structure," and substituted "interior surfaces, porches, and exterior surfaces to which children may be commonly exposed" in order to exclude industrial and commercial building maintenance use (S. Rep. No. 91-1432, 91st Cong., second session 4-5(1970)).

Again it is not reasonably foreseeable that industrial maintenance coatings would be misused and applied to a household surface accessible to children. Large volume users purchase these products directly from manufacturers, and these products are generally unavailable for use around the household. Some retail outlets may stock and sell certain lines of these coatings in limited volume to smaller industrial accounts. Such industrial maintenance coatings normally are labeled "Intended for professional use only and not for retail sale." In addition, they will bear the lead warning label required by the proposed amendment. Thus, the possibility of household use is virtually eliminated.

3. *Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses, and for identification marking of industrial buildings).* These paints or coatings, applied freehand or by hand using a stencil or similar technique, are used to present a graphic image or convey a message. On the basis of intended use and because of a general lack of access by household consumers and children to either the coating or coated surface, graphic arts coatings should be excluded from the regulation.

While these coatings may be stocked by some dealers, they are intended principally for use by professional sign painters for the application of colors to billboards, billboard structures, road signs, and similar items and for identification markings of industrial buildings and the equipment installed therein. Most of these coatings are used only under

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specific shop conditions for application to plastic and metal surfaces, such as illuminated signs advertising particular businesses (e.g., service stations), or for road-directional markers.

The need for such contrasting colors is mandatory for these types of identification. Existing technology provides no substitute materials for lead which will provide the brilliance, color permanence, and film durability necessary for extended periods of service, particularly under the temperature, sunlight, and humidity conditions of outdoor exposure. Furthermore, for many of these uses, such as application to road signs, these coatings are baked on. No acceptable nonlead colorants, which can withstand such baking, are presently available.

4. *Touchup coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances.* These coatings are packaged in small containers or in aerosol containers for use by the consumer in making minor surface repairs to his automobile, household appliance, or other mechanical equipment which may be found in the vicinity of his home. While intended primarily for use in and around the household, they are neither intended nor suitable for application to large surface areas accessible to children. The hard metal surface of the vehicles, appliances, or other equipment on which these coatings are applied do not lend themselves to chewing by children. The very thin, hard coating film on such surfaces cannot be removed and ingested by chewing.

These coatings are packaged and marketed in small quantities, discouraging their use on anything except an extremely small area. As with automotive refinish coatings, they generally are not suited for use other than as intended. Furthermore, to insure against any misuse of this product, each container will carry the required labeling, warning of the lead content and restricting the use of the product.

5. *Exterior marine coatings for small craft application.* The bulk of marine coatings are marketed for industrial use only, are sold in containers not suitable for use in and around the household, and, therefore, are outside the coverage of the act. Yet, marine coatings also are sold in significant volume at retail for use by consumers in coating small craft, and these coatings could be found in or around the household.

Lead is an essential ingredient for these coatings, primarily for the same reasons it is needed in industrial maintenance. Lead is a necessary component for corrosion control; there are no satisfactory substitutes. As with automative refinish coatings, lead is needed in marine coatings to provide resistance to weathering and other environmental conditions.

When used for their intended purpose, marine coatings do not pose a lead hazard to children since the coated surfaces are not accessible to them. Furthermore, it is not reasonably foreseeable that such coatings would be misused for other purposes in or around a household because other, better suited, less costly coatings are more readily available. Finally, the proposed warning label would clearly indicate to the consumer that the coating should not be applied on any areas accessible to children.

6. *Exterior rubber-based roof coatings.* These coatings are unique in that they are rubber-based as opposed to the types of materials used in other coatings. Lead oxides are the only known materials available for curing the liquid coatings when applied to surfaces such as roofs where waterproofing is essential. Oxides of no other metals exert any influence on the cure of these rubberized coatings. In addition, lead oxides are required for improved water resistance. These surfaces are obviously not accessible to children and, thus, the intended or reasonably foreseeable use will not create a health hazard for children.

7. *Exterior wood primer coatings for wood siding containing extractives (products marketed solely for use on redwood or cedar).* Lumber used for fabrication of siding materials may at times be cedar or redwood, each of which contains water-soluble materials which can be leached by moisture and deposited at or near the paint surface. These staining chemicals can have increased solubility in the high pH of emulsion paints and can accentuate the development of unslightly stains on the paint film. A lead compound primer is used when the bare substrate is cedar or redwood, in order to insolubilize the stains before they reach the topcoat. Continued manufacture and sale of exterior staining wood primers of this type, which contains lead, is necessary for this limited purpose.

We do not believe that the use of this product poses a reasonably foreseeable lead hazard to children for each of the following reasons:

a. A lead-containing primer need only be used once, and thus, there is no buildup of layers of lead-containing paint, which is recognized as a primary cause of lead poisoning;

b. Exterior house siding is not readily accessible to children in the sense that porch railings and ornamental surfaces are accessible;

c. Staining, as distinguished from nonstaining, woods are not widely used for siding; and

d. Some of the primer penetrates the wood substrate and thus, should the coating peel, little, if any, of the primer peels with it.

Summary

While a number of these special purpose coatings may be found in or near the household in packaged form, no lead hazard to children arises either before or after they are applied to the surfaces for which they are intended. Only "household" paints that are intended to be applied to surfaces accessible to children can pose the lead hazard sought to be prevented by the regulation in question.

We are not aware of any data, including reports in medical literature or human experience, which indicate that children have ingested dried paint films from the types of surfaces on which the products described herein are applied, nor is it reasonably foreseeable that such ingestion would occur. Additionally, considering the inaccessibility of the surfaces to which these paint films are applied and/or the hardness of the film or substrate to which they are applied, ingestion of these products after application is not reasonably foreseeable. Finally, and as previously pointed out, the likelihood of misuse of these products is exceedingly remote.

Accordingly, this petition is submitted in the interest of establishing, for both the consumer and the industry, clarity and certainty with respect to the scope of the subject regulation. This would also avoid the possibility of unwarranted regulatory action resulting from a lack of such clarity and certainty and provide a sound enforcement basis for labeling these classes of products.

Procedure

Since this petition is filed prior to the implementation date (December 31, 1972) of the lead order, it is requested that the publication of this petition have the effect of suspending the effective date of the order, pending review of comments and promulgation of a final order in this matter, only as it applies to those paints and similar surface coating materials which petitioners submit should not be subject to the order. Without such a suspension, the manufacture and distribution of the products would be totally disrupted. Manufacturers have not known and still do not know whether to continue or discontinue the marketing of these specialized coatings since there is a substantial unresolved question of their status under the lead order. Additionally, until this question is finally resolved by a final order, customers of these manufacturers, such as distributors or users having a secondary retail trade, cannot with confidence continue to purchase such products. This is because it may be necessary for them to introduce the products into interstate commerce subsequent to the December 31, 1972, implementation date. This petition is not intended to affect the implementation date of the lead standards as they apply to other paints and surface-coating materials.

An additional factor for consideration relates to the labeling required by the proposed amendment. Until the Commissioner determines by regulation the acceptable or desirable label statements for the special-purpose coatings under consideration, manufacturers cannot with confidence label or relabel new production. It will be necessary, therefore, to consider lead time for an implementation date for such labeling as may be required.

Since this petition was received prior to the implementation date (December 31, 1972) of § 191.9(a)(6)(i)(b), the publication of this proposed amendment shall have the effect of suspending said implementation date, only as it applies

to those paints and similar surface-coating materials as described in this proposal, pending review of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.-9(a)(6)(i)(b) as it applies to other paint and similar surface-coating materials.

This proposal is being issued pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(q)(1)(B), (2), 74 Stat. 372, as amended by 80 Stat. 1304; 15 U.S.C. 1261 (q)(1)(B), (2)) and the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055, as amended; (21 U.S.C. 371(e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120). Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 29, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-20789 Filed 12-4-72;8:45 am]

Social and Rehabilitation Service

[45 CFR Parts 201, 206]

PUBLIC ASSISTANCE PROGRAMS

Payments for Ineligible Cases and Overpayments for Eligible Cases; Exclusion of Expenditures

Notice is hereby given that the regulations set forth in tentative form below are proposed by the Administrator, Social and Rehabilitation Service, with the approval of the Secretary of Health Education, and Welfare. The proposed regulations relate to the programs of financial and medical assistance, authorized under title I, IV-A, X, XIV, XVI, and XIX of the Social Security Act.

The proposed regulations would exclude from Federal financial participation, all expenditures for payments for ineligible cases and overpayments for eligible cases.

Prior to the adoption of the proposed regulations, consideration will be given to any comments, suggestions, or objections thereto which are submitted in writing to the Administrator, Social and Rehabilitation Service, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington, DC 20201 within a period of 20 days from the date of publication of this notice in the FEDERAL REGISTER. It is the policy of the Department that 30 days' notice will be given for proposed rule making in the formulation of rules and regulations governing the Department's grant programs. Compliance with such procedures, however, would involve delay in implementing urgently needed measures, found to be necessary for the proper and efficient administration of the assistance programs, which are to become effective January 1, 1973. Such delay would be contrary to the public interest. Accordingly, we find that there is good cause to reduce the usual period of notice. Comments received will be available for public inspection in room 5121 of the Department's offices at 301 C Street SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (area code 202—963-7361).

The proposed regulations are to be issued under section 1102, 49 Stat. 647, 42 U.S.C. 1302.

Dated: November 29, 1972.

JOHN D. TWINAME,
Administrator, Social and Rehabilitation Service.

Approved: November 29, 1972.

ELLIOT L. RICHARDSON,
Secretary.

1. Section 201.5 of Part 201, of Chapter II, Title 45 of the Code of Federal Regulations is revised to read as set forth below:

§ 201.5 Grants.

To States with approved plans, grants are made, prior to the commencement of each quarter, for estimated expenditures under the plan for assistance, services, training, and administration. The amount of the quarterly grant award is based upon estimates submitted by the State, containing information required by the Administrator, and such other information available to the Department as may be necessary to estimate expenditures properly subject to Federal financial participation.

(a) *Form and manner of submittal.* (1) Time and place: The estimates for public assistance grants for each quarterly period must be forwarded to the Department of Health, Education, and Welfare, Social and Rehabilitation Service, Washington, D.C. 20201, Attention: Office of Financial Management, with copy to the regional office 45 days prior to the period of the estimate. They include a certification of State funds available and a justification statement in support of the estimates. A statement of quarterly expenditures and any necessary supporting schedules must be forwarded to the same addresses not later than 30 days after the end of the quarter. An annual supplement to the statement of expenditures, for accounting for social service expenditures in accordance with the limitations of section 1130 of the Social Security Act, must also be forwarded to the same addressees not later than 60 days after the end of the Federal fiscal year.

(2) Description of forms: "State Agency Expenditure Projection—Quarterly Projection by Program" represents the State agency's estimate of the total amount and the Federal share of expenditures for assistance, services, training, and administration to be made during the quarter for each of the public assistance programs under the Act. From these estimates the State and Federal shares of the total expenditures are computed. The State's computed share of total estimated expenditures is the amount of State and local funds necessary for the quarter. The Federal share is the basis for the funds to be advanced for the quarter. The State agency must also certify, on this form or otherwise, the amount of State funds (exclusive of any balance of advances received from the Federal Government) actually on hand and available for expenditure; this certification must be signed by the executive officer of the State agency submitting the estimate or a person officially designated by him, or by a fiscal officer of the State if required by State law or regulation. (A form "Certificate of Availability of State Funds for Assistance and Administration during Quarter" is available for submitting this information, but its use is optional.) If the amount of State funds (or State and local funds if localities participate in the program), shown as available for expenditures is not sufficient to cover the State's proportionate share of the amount estimated to be expended, the certification must contain a statement showing the source from which the amount of the deficiency is expected to be derived and the time when this amount is expected to be made available.

(3) The State agency must also submit a quarterly statement of expenditures for each of the public assistance programs under the Act. This is an accounting statement of the disposition of the Federal funds granted for past periods and provides the basis for making the adjustments necessary when the estimate for any State for any prior quarter was greater or less than the amount the State actually expended in that quarter. The statement of expenditures also shows the share of the Federal Government in any recoupment, from whatever source, of expenditures claimed in any prior period, and also in expenditures not properly subject to Federal financial participation which are acknowledged by the State agency or have been revealed in the course of an audit.

(4) Effective for quarters beginning with the quarter commencing January 1, 1973, all expenditures for payments of financial and medical assistance for ineligible individuals or families and overpayments for eligible cases shall be excluded from State estimates and expenditure reports.

(b) *Review.* The State's estimates are analyzed by the regional office staff and are forwarded with recommendations as required to the central office. In computing the grant, the central office reviews the State's estimate, other relevant information, and any adjustments to be made for prior periods. Relevant information as to payments for ineligible individuals or families and overpayments includes the most recent data available from reports (as required under § 205.40 of this chapter) on quality control reviews of State samples or the national

§ 51.59 Operations and operating procedures.

* * * * *

(c) * * *

(8) Submit to the Chief of the Fresh Products Standardization and Inspection Branch, Fruit and Vegetable Division, Agricultural Marketing Service, for approval prior to printing, drawings or printers' proofs of each packer's or distributor's label bearing or referring in any manner to official inspection legends or grade marks.

* * * * *

(Secs. 203, 205, 60 Stat. 1087, as amended, 1090 as amended; 7 U.S.C. 1622, 1624)

Dated: December 26, 1972.

E. L. PETERSON,
Administrator,
Agricultural Marketing Service.

[FR Doc.73-87 Filed 1-3-73;8:45 am]

Commodity Credit Corporation

[7 CFR Part 1430]

PRICE SUPPORT PROGRAM FOR MILK

Loans, Purchases, and Other Operations

Notice is hereby given that the Secretary of Agriculture, under authority of section 201(c) of the Agricultural Act of 1949, as amended (63 Stat. 1051, as amended; 7 U.S.C. 1446), and sections 4 and 5 of the Commodity Credit Corporation Charter Act, as amended (62 Stat. 1070, as amended; 15 U.S.C. 714b and 714c), is considering the terms and conditions of the price support program for milk, for the 1973-74 marketing year beginning April 1, 1973, including the general level of prices to producers for milk and the prices for and terms of purchase by CCC of butter, nonfat dry milk, and cheddar cheese. Section 201(c) of the Agricultural Act of 1949, as amended, provides as follows: "The price of milk shall be supported at such level not in excess of 90 per centum nor less than 75 per centum of the parity price therefor as the Secretary determines necessary in order to assure an adequate supply. Such price support shall be provided through purchases of milk and the products of milk."

Consideration will be given to any data, views, and recommendations which are submitted in writing to the Director, Livestock and Dairy Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture, Washington, D.C. 20250. In order to be sure of consideration, all submissions must be received by the Director not later than 30 days after publication of this notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Director during regular business hours (8:15 a.m.-4:45 p.m.). (7 CFR 1.27(b))

Signed at Washington, D.C., on December 22, 1972.

GLENN A. WEIR,
Acting Executive Vice President,
Commodity Credit Corporation.

[FR Doc.73-125 Filed 1-3-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 3]

VITAMIN A AND VITAMIN D

Proposed Statement of Policy; Correction

The Commissioner of Food and Drugs issued a proposed statement of policy on the use of vitamin A and vitamin D which was published in the FEDERAL REGISTER of Thursday, December 14, 1972 (37 FR 26618). The provisions of the proposed new sections should be corrected as follows:

1. The proposed § 3.—— *Vitamin A preparations for oral use as drugs* is amended by deleting paragraph (b)(3), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c) to read as set forth below.

§ 3.—— Vitamin A preparations for oral use as drugs.

* * * * *

(b) * * *

(3) [Deleted]

(c) Preparations containing 10,000 or less I.U. of vitamin A per dosage unit will be regarded as misbranded if their recommended daily dosage exceeds 10,000 I.U.

* * * * *

2. The proposed § 3.—— *Vitamin D preparations for oral use as drugs* is amended by deleting paragraph (b)(3), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c) to read as set forth below.

§ 3.—— Vitamin D preparations for oral use as drugs.

* * * * *

(b) * * *

(3) [Deleted]

(c) Preparations containing 400 or less I.U. of vitamin D per dosage unit will be regarded as misbranded if their recommended daily dosage exceeds 400 I.U.

* * * * *

Dated: December 26, 1972.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-132 Filed 1-3-73;8:45 am]

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposed Exemption of Artists' Paints and Related Materials

An order was published in the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5229), classifying certain lead-containing paints and other similar surface-coating materials as banned hazardous substances. This regulation (21 CFR 191.9 (a)(6)) was promulgated under section 2(q)(1)(B) of the Federal Hazardous Substances Act.

Section 191.9(a)(6)(i) declares as a banned hazardous substance any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around a household that is shipped in interstate commerce between December 31, 1972, and December 31, 1973, and that contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film. The effective date of this part of the regulation was confirmed in the FEDERAL REGISTER of August 10, 1972 (37 F.R. 16078).

Since the promulgation of said banning regulation, the Food and Drug Administration has received many inquiries and adverse responses concerning the banning of artists' paints due to their lead content. These deal specifically with lead carbonate (also known as white lead, flake white, cremnitz white, and silver white). Interested persons state (1) that lead is a necessary component of artists' paints, (2) that a satisfactory substitute for lead is not currently available, and (3) that although these products are both intended and packaged in a form suitable for use in and around a household, it is not likely that children will ingest the dried paint film.

Having considered the responses and other relevant material, the Commissioner of Food and Drugs proposes to exempt artists' paints and related materials from classification as a banned hazardous substance. If this proposal is adopted these materials will still be subject to other provisions of the Federal Hazardous Substances Act and regulations promulgated thereunder.

Therefore, pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(q)(1)(B), (2), 74 Stat. 374, as amended 80 Stat. 1304; 15 U.S.C. 1261 (q)(1)(B), (2)) and the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055, as amended; 21 U.S.C. 371 (e)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that § 191.9(a)(6) be amended by adding thereto a new subdivision (i)(d), as follows:

§ 191.9 Banned hazardous substances.

(a) * * *

(6)(i) * * *

(*d*) The provisions of this subdivision (i) do not apply to artists' paints and related materials.

* * * * *

Publication of this proposal in the FEDERAL REGISTER shall have the effect of suspending the implementation date (De-

cember 31, 1972) of § 191.9(a) (6) (i) (b) only as it applies to artists' paints and related materials, pending review of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.9(a) (6) (i) (b) as it applies to other paints and similar surface-coating materials.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: December 26, 1972.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-20 Filed 1-3-72;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 91]

[Docket No. 11350; Notice No. 72-35]

VFR WEATHER MINIMUMS

Notice of Proposed Rule Making

The Federal Aviation Administration is considering amending Part 91 of the Federal Aviation Regulations by revising § 91.105 to prescribe distance from cloud minimums for aircraft operating 1,200 feet or less above the surface outside controlled airspace.

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments, as they may desire. Communications should identify the regulatory docket or notice number and be submitted in triplicate to: Federal Aviation Administration, Office of the General Counsel, Attention: Rules Docket, AGC 24, 800 Independence Avenue SW., Washington, DC 20591. All communications received on or before March 22, 1973, will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the rules docket for examination by interested persons.

I. *Background.* This notice of proposed rule making follows advance notice of proposed rule making (ANPRM) 71-24 (36 FR 17052) which was issued on August 23, 1971. That ANPRM was issued to obtain comments on the adequacy of existing basic VFR weather minimums below 10,000 feet MSL in controlled and uncontrolled airspace.

Approximately 600 of the 730 comments received in response to the notice stated that existing VFR minimums are adequate. Despite the fact that views were solicited on the adequacy of all minimums in controlled airspace below 10,000 MSL, many comments were devoted solely to opposing the results of a pilot survey which indicated that some individuals favored an increase in visibility from 3 to 5 miles. Since many of the comments were preoccupied with this one issue, the amount of information submitted on other aspects of the ANPRM, including distance from cloud requirements, was small. This notice is issued to obtain more adequate public comment with respect to distance from cloud requirements.

II. *Within controlled airspace.* There was overwhelming opposition to increasing VFR minimums in controlled airspace. As indicated above, a large proportion of the comments was directed to the issue of whether or not to increase the visibility minimum to 5 miles (below 10,000 feet). Commentators considered this unacceptable for two reasons. First, they stated that the estimated restriction to all kinds of general aviation activity would be very serious, due to the poor visibility prevailing in many parts of the United States a large portion of the time. Second, they stated that a visibility minimum of 5 miles would not, in itself, enable a pilot to see and avoid another aircraft any sooner than with 3 miles visibility, because, they stated, it is almost impossible to see a small aircraft 5 miles away.

Rule making on the visibility aspects of the ANPRM is being deferred for further study of these comments, particularly since available statistics indicate that most near midair collision incidents occur during daylight hours and when the visibility is in excess of 5 miles. This would indicate that a mere increase in visibility minimums may involve an increased burden on the airspace user without a corresponding increase in safety in controlled airspace.

III. *Outside controlled airspace.* There were few comments directed specifically to adequacy of minimums in uncontrolled airspace. The majority of these stated that the minimums are adequate and no changes are necessary. However, some commentators did support more restrictive requirements. The National Transportation Safety Board (NTSB) commented that in many instances uncontrolled airspace is utilized for training, transition and aircraft familiarization for new or low-time pilots, that these activities plus a low-experience level inherent in training activities tend to increase hazards, and that therefore greater cloud clearance and visibility should be required. The NTSB stated that the weather minimums in uncontrolled airspace should be the same as those in controlled airspace below 10,000 feet. The FAA is giving due consideration to all aspects of this recommendation, and believes that the Board may be correct with respect to distance from clouds at and below 1,200 feet outside controlled airspace. This notice requests further public comment on this point.

Several other comments suggested that the minimums should be increased. Some favored an across-the-board visibility requirement of 3 miles with no change in the existing "clear of clouds" requirement below 1,200 feet AGL. Others suggested some intermediate or sliding scale of visibility values, while a few recommended some form of cloud clearance criteria in uncontrolled airspace below 1,200 feet. In addition, several commentators noted the complexity of the existing weather minimums. The FAA agrees that the present rules are complex, and that one of the complicating factors is the "clear of clouds" requirement outside controlled airspace at and below 1,200 feet above the surface. The proposed amendment, in addition to responding to safety considerations, would eliminate this factor.

As several comments indicated, a requirement to avoid clouds by a moderate distance could prevent a pilot from inadvertently entering clouds since the distance between being "clear of" clouds and "in" clouds is slight. Specifying a moderate minimum distance would introduce a new safety factor in the VFR rules outside of controlled airspace.

Since Notice 71-24 covered many areas and the responding comments were necessarily somewhat fragmented, the FAA believes that the public should have an opportunity to focus on this one aspect of the VFR minimums. In addition to the subject matter of this proposal, there are other subjects either discussed in the ANPRM or generated by it that are receiving consideration and which may lead to future proposals.

In consideration of the foregoing, it is proposed to amend Part 91 of the Federal Aviation Regulations by amending § 91.105(a) by deleting, from the table, the words "clear of clouds" and by substituting the words "500 feet below," "1,000 feet above," and "2,000 feet horizontal," therefor.

This amendment is proposed under the authority of sections 307 and 313(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348, 1354(a)), and section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on December 22, 1972.

WILLIAM M. FLENER,
Director, Air Traffic Service.

[FR Doc.73-144 Filed 1-3-73;8:45 am]

Federal Highway Administration

[49 CFR Part 393]

[Docket No. MC-22; Notice No. 72-25]

MOTOR CARRIER SAFETY REGULATIONS

Vehicle Interior Noise Levels

The Director of the Bureau of Motor Carrier Safety proposes to amend the motor carrier safety regulations to establish a maximum interior sound level for commercial motor vehicles operated in interstate or foreign commerce.