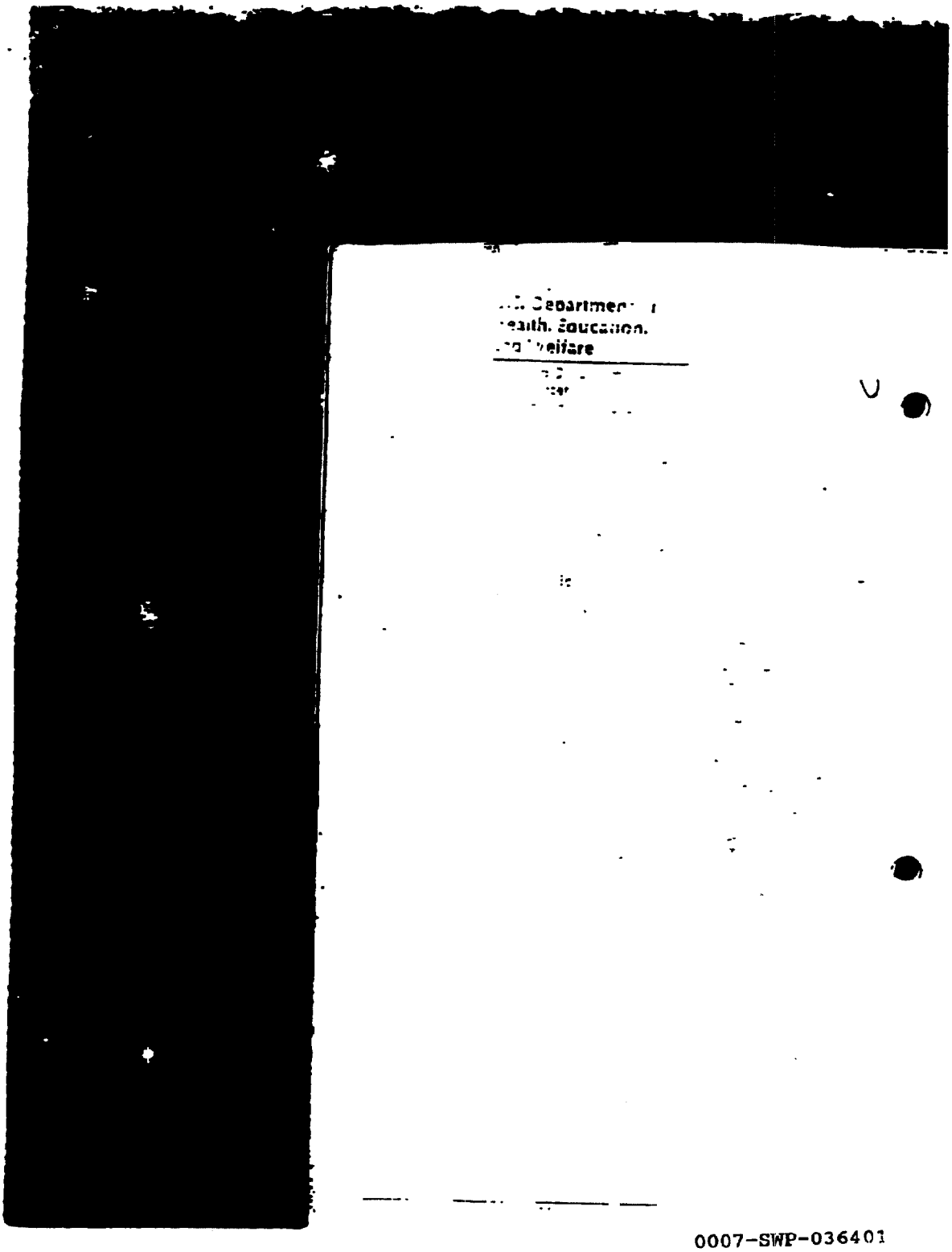

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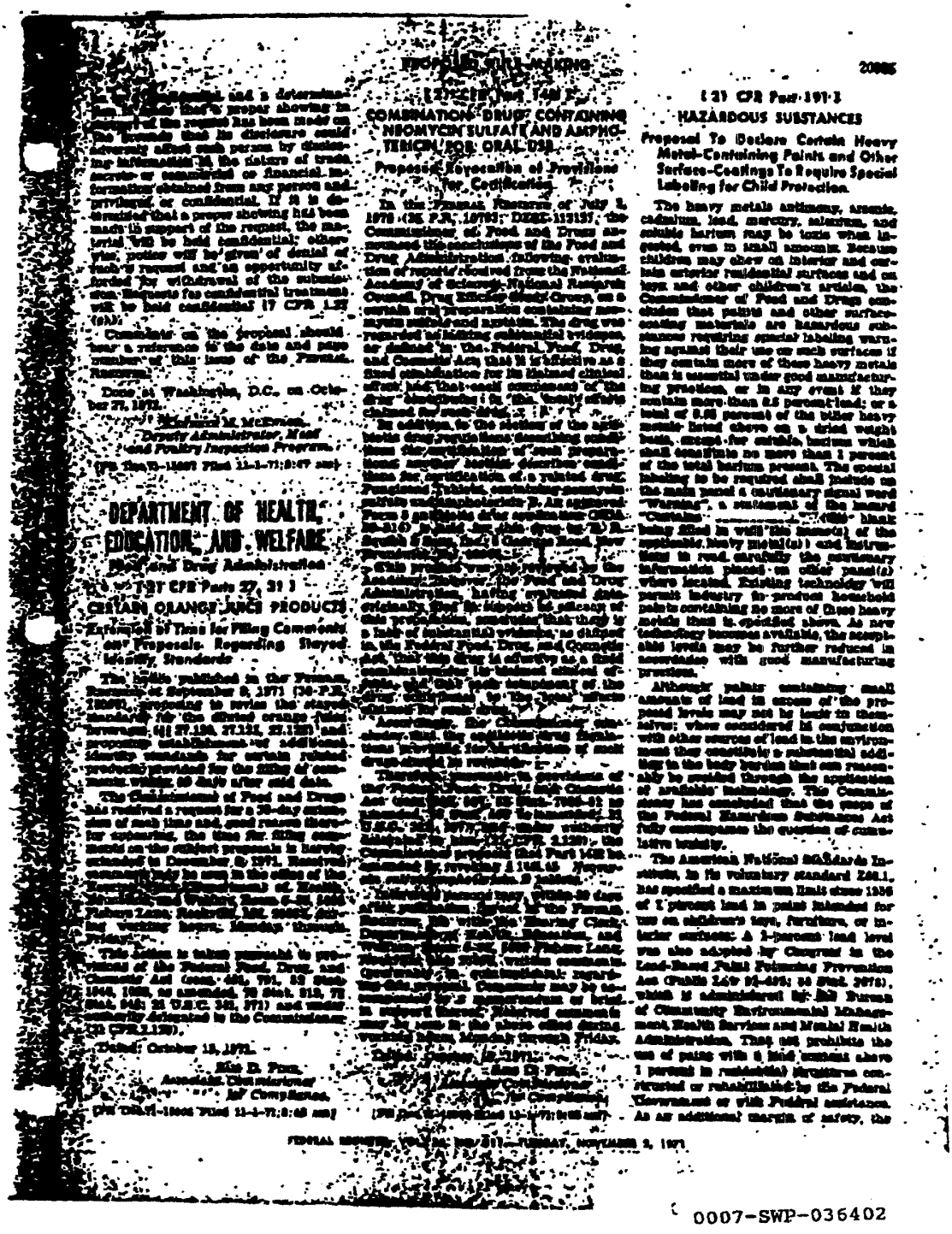

[illegible] and a determination [illegible] that a proper showing in support of the request has been made on the grounds that its disclosure could adversely affect such person by disclosing information in the nature of trade secrets or commercial or financial information obtained from any person and 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 (a)).

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.

[illegible] M. McEwen,
Deputy Administrator, Meat and Poultry Inspection Program.

[FR Doc.71-15007 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 8, 1971 (36 F.R. 18090), 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. 313, 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner (21 CFR 1.120).

Dated: October 15, 1971.

[illegible] D. Fine,
Associate Commissioner for Compliance.

[FR Doc.71-15006 Filed 11-1-71;8:48 am]

PROPOSED RULE MAKING

[21 CFR Part 148]

COMBINATION DRUG CONTAINING NEOMYCIN SULFATE AND AMPHOTERICIN FOR ORAL USE

Proposed Revocation of Provisions for Certification

In the FEDERAL REGISTER of July 3, 1970 (35 F.R. 10793; DESI 112137), 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, Pungizone Tablets, containing neomycin sulfate and amphotericin B. An approved Form 5 antibiotic drug application (NDA 50-316) 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 the approval 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 provided for certification of such drugs should be revoked.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046-52 as amended, 70 Stat. 313 as amended; 21 U.S.C. 341, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 148 be amended by revoking § 148.45 *Neomycin sulfate-amphotericin 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 15, 1971.

[illegible] D. Fine,
Associate Commissioner for Compliance.

[FR Doc.71-15008 Filed 11-1-71;8:48 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 1956 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 amount 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 accidental injury and even death resulting from the ingestion of the dried film of old household 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 2(q) 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 that Act, that require special labeling, be specified herein if such paints and other surface-coating materials contain, on the dried weight basis, more than 0.5 percent lead; or a total of more than 0.06 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 the 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), 2(s), and 3(b); 74 Stat. 372, 378–379; 15 U.S.C. 1261, as amended, 81 Stat. 1906; 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 § 191.1(a) and that a new subparagraph be added to § 191.7(b), as follows:

§ 191.5 Products declared to be hazardous substances under section 2(q) 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:

* * * * *

(3) Paint and other surface-coating materials produced or shipped in interstate commerce after the effective date of

Dated: October 25, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-15997 Filed 11-1-71;8:45 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)), requesting the issuance of a regulation under sections 2(q)(1)(B) and 3(a)(2) of the Federal Hazardous Substances Act (74 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, professor at Georgetown University Law Center, Anthony L. Young, student, Mary Wm. O'Brien, student, William R. Ryan, U.S. Congressman, Jane Fonda, actress, and Benjamin S. Rothschild, M.D.

The petitioners propose that § 191.5 of the hazardous-substances regulations be amended by adding thereto new paragraph (a)(3) as follows:

§ 191.5 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 by reason of 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:

* * * * *

(3) Paint containing lead, except for exhibits drawn which is reasonable under whatever could preclude from its presence, as measured by the atomic absorption method, intended for interior or exterior use, and packaged in a form suitable for use in the household as defined by § 191.1(a).

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

[illegible]

[illegible]

[illegible]

children, a child with plum ingesting 1 gram of lead based paint (5 percent lead by weight) would absorb daily with intake 10,000 micrograms of lead, of which 1,000 micrograms will be retained. In addition to direct ingestion by eating flaking paint, a child will be exposed to from 10 to 300 micrograms of lead from other environmental sources. (Engel, Ronald R., "Health Hazards of the Environmental Lead," at Table 2 (April 1971).

It is known that blood levels of above 60 micrograms per HUNDRED of blood represent undue exposure to and absorption of lead. "Hearings on H.R. 17926, H.R. 18084, H.R. 14704, 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 is treated as a medical emergency. Id. While Engel in his paper has extrapolated the effect of lead intake in children with plum, at 4-6, the same could be done with 5 percent lead paint to theorize the result in children who ingest paint flakes.

Dr. Mia Tuomy, Dr. Rohes found that an adult man had 2,000 micrograms of lead daily. In addition to the usual amounts in his diet, he ingested a pinch lead level after 4 months of 50 micrograms lead per 100 grams whole blood. It was estimated that he would have achieved a "safe" level of 30 micrograms lead per 100 grams whole blood if ingesting had continued for 4 additional months. Kehoe, R. A., 24 "Ann. Rep. Ann. Pub. Hlth. Hyg." 81-87, 101, 135-145, 177-202 (1933). Dr. Engel has estimated that would for 60 micrograms per kilogram body weight for a 70 kilogram man. If a child with plum weighing 20 kilograms ingested lead to the same degree as Kehoe's subject, an Engel has estimated, then a proper assumption would be that a daily supplement of 400 micrograms lead would produce toxicity within 2 months. A child ingesting a 1 gram chip of 1 percent lead based paint would have a daily intake of almost 30-times the amount of Kehoe's subject. Obviously, merely 20 this rate would produce an acute medical emergency much more quickly than Kehoe forever 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 must be protected from lead in the environment. The only adequate way to protect him is to eliminate the lead hazard from the environment. It is within that hazard which is the art for the paint industry to eliminate lead (except for minute traces) from paint. "Statement" (the H.R. 17926)" supra at 502. Americans have been FIRST into a feeling of security with regard to today's paints. See EPA, "Environmental Lead and Public Health," at 60 (March 1971). Many believe that lead in paint has been banned. For the city of New York has around paints for interior use with up to 10.5 percent lead levels on dozens of thousands walls. The Sun Times, July 30, 1971, at 1, Section 6, 1971, at 20. This despite the country's LEAST stringent 0.06% and a law banning the sale of paint for interior use with more than 0.5 percent lead content which was adopted by the [illegible].

Warning labels are, however, abysmally 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 kitchen and the bedroom. The generation that this proposed regulation seeks to protect is yet unborn. Their parents are unborn. It would be impossible to communicate that warning to [illegible] would have any significant impact on the future children of America. Moreover, there is no evidence that existing warning labels are adequate for their intended purpose. The parents of the children and the children will have no opportunity to read the warning labels of the occupation.

It is not necessary to weigh the advantages of lead based paint against the health and welfare of the parents, children and the future children. The paint industry can produce paint without lead. (except for minute traces) as developed by the private abatement method. Petitioners therefore urge the Commissioner of Food and Drugs to proceed with all deepened to publish the proposal in the Federal Register in order that all interested persons may present their views thereon.

Interested persons may, within 90 days after publication hereof in the Federal Register, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5-66, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quadruplicate) 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 20, 1971.

A. CARLTON LAWSON,
Commissioner of Food and Drugs.

[FR Doc.71-16111 Filed 11-1-71;8:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 568]

(Docket No. 71-12; Notice 1)

MANUFACTURER IDENTIFICATION

Proposed Motor Vehicle Safety Requirements

The purpose of this proposed amendment is to add Part 568 to Title 49, Code of Federal Regulations, to (1) provide for the assignment of "manufacturer identification", as defined, Part 568, Vehicles Manufactured in Two or More Stages.

A proposed notice of proposed rule making published on April 30, 1971 (36 FR 7709), proposed a new Part 568 which would require manufacturers of motor vehicles and of motor vehicle equipment to identify motor vehicles and motor vehicle safety equipment subject to Federal Motor Vehicle Safety Standards and a description of the manner in which they produce. A notice of hearing on that part is published in this issue of the Federal Register, 36 F.R. [illegible]

In formulating [illegible] a recurring issue was the problem of identifying vehicles manufactured in two or more stages. It was noted that while the proposed regulation clearly covers intermediate and final stage manufacturers (as defined in Part 568), it might be necessary to include 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 568 of Title 49, Code of Federal Regulations:

1. § 568.4 would be amended to read as follows:

§ 568.4 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 (a)(2) of § 568.5 would be amended to read as follows:

§ 568.5 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.

(a) * * *

(2) 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 class 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 vehicle; Motor homes with GVWR from 8,500 to 10,000 pounds. Final-stage manufacturer [illegible] body to base 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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composition and labeling prescribed by § 27.160 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 5 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 1.15 percent but more than 5 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 phrase 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 5 percent orange juice or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 5 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 § 27.160 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 5 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 measures of water per volume of concentrate for orange flavored drink required to produce orange flavored drink conforming to the requirements for composition prescribed by § 27.160.

§ 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 § 27.160 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 5 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. 1046 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.72-3708 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 3, 1971 (36 F.R. 20868), 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 (§ 191.3(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. 20868) 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

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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 consumer, 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 0.06 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 point 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.

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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.

The National Paint and Coatings Association, which represents more than 900 companies, has notified the Commissioner that it anticipates its members can produce by January 1976 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. 3782) 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 3(b)(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 proposing amendment of the regulation. Pursuant to 21 CFR 191.301, 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. 3782), 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. 1304-06; 15 U.S.C. 1261 (f)(1)(A), (q)) and the Federal Food, Drug, and Cosmetic Act (secs. 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 (8) 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:

• • • • •

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

(a) Is shipped in interstate commerce after December 31, 1973, and contains lead components 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, 1973, and December 31, 1975, and contains lead components 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

(c) 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 components 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, 1973, and December 31, 1975, and bears any paint or other similar surface-coating material containing lead components 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 the date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5-58, 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. 1304-06, 15 U.S.C. 1261(f)(1)(A), (q); secs. 701 (e), (f), (g), 52 Stat. 1055-59 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.72-3750 Filed 3-10-72;12:50 p.m.]

Title 26—INTERNAL REVENUE

[T.D. 7187]

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 221(d) of the Tax Reform Act of 1969 (83 Stat. 611), relating to rehabilitation of low-income housing, was published in the FEDERAL REGISTER (35 F.R. 12460). After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the amendments so 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. 631; 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.

FRANKLIN W. KNEDISH,
Acting Assistant Secretary of the Treasury.

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