

FROM: J. E. Peters

CITY Cleveland, #20

ANSWERING LETTER OF

SUBJECT FEDERAL HAZARDOUS SUBSTANCES ACT
Lead Paint

E.G.S. DATE
MAR 27 1972
APV - [initials]
Aob - [initials]

March 16, 1972

FOR W. D. Kinsell, UCB

cc: G. L. Bechtel, UCB
H. J. Horton, UCB
H. J. Kiefer, UCB
L. P. Long, UCB
T. J. Walsh, UCB
C. W. Wright, UCB

Attached is a copy of the new FDA regulations covering paint containing lead. The first 84 pages of the attachment contain miscellaneous background reiterating the positions of groups which were supporting and fighting the regulation. Commencing at the bottom of page 9 at Article 191.9, the regulation governing paint products containing lead is set forth. This regulation becomes law on April 21, 1972. Basically we will not be permitted to ship in interstate commerce after December 31, 1972 any coating which could be used in or around the household which contains in excess of 0.5% lead. After December 31, 1973, we will not be permitted to ship in interstate commerce any such coatings which contain in excess of 0.06% lead.

The amount of lead allowable is based upon the total weight of the contained solids or dried paint film.

Secondly, any toy or other article intended for use by children will not be permitted to be shipped in interstate commerce if it bears a coating in excess of the allowable percentages of lead as stated above corresponding to the time periods stated above.

Assuming that other federal agencies within the Department of Health, Education & Welfare adopt the percentages outlined above, it is my interpretation that the term "paint suitable for use in or around the household" will be expanded to include all coatings in our industrial maintenance line, plus our industrial finishes which are destined to be applied to substrates accessible to children, i.e., prefinished paneling, window sills, railings, etc.

The phrase "shipped in interstate commerce" is subject to debate. I have no doubt that any products shipped from our manufacturing plants to our own outlets or to dealers, etc. would be products shipped in interstate commerce. Questions arise as you go down the chain of distribution. It is my opinion that deliveries from our distribution units to dealers would also fall within the term interstate commerce as well as would shipments between our own units, i.e., from district centers to branches. An individual who purchases products at one of our stores or from one of our dealers and carries the product home with him would not fall within the definition of interstate commerce. However, the deliveries of our products to a

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painting contractor from our distribution unit, especially if the shipment is across state lines, would bring the shipment or transfer within the definition. Conversely, a contractor who picked up the products at our outlet and carried them across state lines would not be shipping the product in interstate commerce. While the shipment of industrial coatings destined for those substrates accessible to children do not fall within the shipment prohibitions, the strategy is to attack the end product banning it as a hazardous substance, and thus forcing the coating supplier to cease shipments of these products.

Section 15 of the Federal Hazardous Substances Act establishes repurchase provisions for banned hazardous substances which require a manufacturer to repurchase upon the request of the customer any banned hazardous substances. This means that if a dealer or a customer has products on his shelf which contain more than the allowable lead content, he can require us to repurchase the product at the price he paid for them, plus any additional expenses incurred in returning the products. Unfortunately the law does not have any time provision which shuts off purchases before a certain time. In fact, Section 15 states that ". . . any article sold by its manufacturer. . . which is a banned hazardous substance (whether or not it was such at the time of its sale) shall be repurchased."

A recent Associated Press article quotes Wilcom W. Jensen, Director of the Bureau of Product Safety, indicating that he favors refunds "back to the beginning of time." In the same article, Mr. Rudolph A. Vignone, Chief of compliance in the Bureau of Product Safety stated "We've tried to set a starting date effective with the child safety law on Jan. 1, 1970 but general counsel (Peter Hutt) insists there be no time cutoff."

In light of the above, the repurchase provisions may turn out to be the biggest headache of this lead paint regulation. I shall continue to keep you informed as matters develop.

John E. Peters

JEP/rem

Attach.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D--HAZARDOUS SUBSTANCES

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

SIMILAR
ORDER CLASSIFYING CERTAIN LEAD-CONTAINING PAINTS AND OTHER 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
(section 191.5(a)(2)) and to be products requiring special labeling
under section 3(b) of the act (section 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

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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 inhouse 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 one 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 touch-up 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. Few comments were received expressed an opinion concerning that [^] the Commissioner's proposal as it related to other heavy metals, and none of them 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" (emphasis supplied). 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

only regulatory action ^{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.

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 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 proposing 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 0.05 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. 3760), 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, 89 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. 943; 21 U.S.C. 371(c), (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 6-39, 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: _____.