GLIDDEN-DURKEE
DIVISION OF SCM CORPORATION
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Please note EDA requirement statement

FROM J. E. Peters DATE March 14, 1972 FOR H. J. Kiefer, UCB

CITY Cleveland, #30

ANSWERING LETTER OF

SUBJECT FDA INQUIRY -- Heavy Metals - Paint

TO
H. J. KIEFER
MAR 15 1972
TDMC

Attached for your review is a publish request from FDA on the subject. Were you aware of this problem? Perhaps we should discuss this before any action is taken.

John E. Peters

JEP/rem

Attach.

GLD012584

[¶ 40,623] Food and Drug Administration Proposed Regulation. Dated February 3, 1972. Published in 37 F. R. 3644, February 18, 1972.

Food Standards—Soda Water—Edible Vegetable Oils—Optional Ingredients—Proposal.—A proposal to amend the standard of identity for soda water to provide for the use of edible vegetable oils as optional ingredients in clouding agents and as carriers for flavoring agents has been issued by the Food and Drug Administration. Views and comments may be filed by April 18, 1972.

See FDC Act § 401, Food volume, ¶ 51,051.

Notice is given that a petition has been filed by the Aromatics International Manufacturing Co., Inc., Atlanta, Ga. 30331, proposing that the standard of identity for soda water (21 CFR 31.1) be amended to provide for the use of edible vegetable oils as optional ingredients in clouding agents and as carriers for flavoring ingredients used in soda water.

Grounds given in support of the petition are (1) That there is a need for a safe substitute for brominated vegetable oils which are no longer permitted to be used in soda water in quantity sufficient to produce the clouding effect desired and (2) that there is a need for an additional safe, edible, relatively flavorless carrier for flavoring.

Accordingly, it is proposed that § 31.1 (21 CFR 31.1) be amended to provide for the optional use of edible vegetable oils as emulsifying, stabilizing, or viscosity-producing agents and as carriers for flavoring ingredients used in soda water.

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 in accordance with authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), interested persons are invited to submit their views in writing (preferably in quintuplicate) regarding this proposal within 60 days [April 18, 1972] after its date of FEDERAL REGISTER publication. Such views and comments should be addressed to the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, and 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.

[¶ 40,624] Food and Drug Administration Request for Data. Dated February 17, 1972. Published in 37 F. R. 3780, February 19, 1972.

Hazardous Substances—Paints and Coatings Containing Heavy Metals—Request for Data.—Paint manufacturers have been asked by the Food and Drug Administration to submit analyses of their interior and general purpose exterior paints and of those paints and coatings applied for use on toys and other children's items and on household items accessible to children. The FDA stated that such data would be of value in preparing a final order based on proposals made by the agency (see ¶ 40,571) and by a group of private citizens (see ¶ 40,572) that certain heavy metals-containing paints be designated as hazardous substances. Manufacturers were requested to state the total amount of each named heavy metal present in the dried paint products, the method used for such determination, the amount of those metals intentionally added, the reason for such addition, and current labels for each analyzed product. The data should be submitted by April 7, 1972.

See Hazardous Substances Act §§ 2(f)(1)(A), 2(q)(1)(A), and 3(a) and (b), Federal volume, ¶ 9061, 9083, 9091, and 9093.

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.

[¶ 40,625] Department of Health, Education and Welfare Memoranda Regarding Human Drug Biological Products. Dated February 18, 1972. Published in 37 F. R. 4004, February 25, 1972.

Administration—Human Drug Biological Products—Redelegation of Authority—Jurisdiction of FDA and DBS.—The responsibility for the regulation of human drug biological products under the FDC Act has been redelegated from the Assistant Secretary for Health and Scientific Affairs, Department of Health, Education and Welfare, concurrently to the Food and Drug Administration and to the National Institutes of Health Division of Biologics Standards. A memorandum of understanding between the two agencies provides that regulations pertaining only to biologicals will be promulgated by the DBS, with FDA approval. All regulations issued by the FDA regarding human drugs will apply to biologicals. The DBS will have primary responsibility for enforcing the FDC Act with respect to biologicals. The FDA will not enforce the Act regarding such products unless requested to do so by the DBS. In emergency situations involving the protection of the public from danger to life or health, DBS will ask the FDA to remove the biological product involved from the market. The agreement also provides for information interchanges between the two agencies.

See Public Health Service Act § 351 and FDC Act § 902, Federal volume, ¶ 1170 and 2275.

[*Redelegation of Authority*]

The following authority delegated to the Assistant Secretary for Health and Scientific Affairs by the Secretary of Health, Education, and Welfare under section 6 of Reorganization Plan No. 1 of 1953 and section 2 of Reorganization Plan No. 3 of 1966 is hereby redelegated to the Commissioner of Food and Drugs and the Director, National Institutes of Health, as follows:

1. Effective this date, each of you is hereby concurrently redelegated the authority vested in me to administer, enforce, and apply all applicable provisions of the Federal Food, Drug and Cosmetic Act, as amended, with respect to those human drugs that are biological products as defined in, and subject to licensing under, section 351 of the Public Health Service Act, as amended (42 U. S. C. 262) and the regulations thereunder, 42 CFR Part 73.