

will provide adequate Class E airspace for IFR operations at Merritt Island Airport.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Cocoa, FL, to accommodate at NDB RWY 11 SIAP and for IFR operations at Merritt Island Airport. The operating status of the airport will be changed from VFR to include IFR operations concurrent with publication of the SIAP.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet Above the Surface of the Earth

* * * * *

ASO FL E5 Cocoa FL [New]

Merritt Island Airport, FL
(Lat 28°20'30"N, long. 80°41'08"W)
Merritt Island NDB
(Lat 28°20'27"N, long. 80°41'18"W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Merritt Island Airport and within 2.5 miles each side of the 127° bearing from the Merritt Island NDB, extending from the 6.3-mile radius to 7 miles northeast of the NDB; excluding that airspace within the Titusville, FL, and Melbourne, FL, Class E airspace areas.

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Issued in College Park, Georgia, on June 16, 1995.

Stanley Zylowski,

Acting Manager, Air Traffic Division, Southern Region.
[FR Doc. 95-15715 Filed 6-26-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 189

[Docket Nos. 82P-0371 and 91N-0165]

Lead-Soldered Food Cans

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food additive regulations to prohibit the use of lead solder to manufacture cans for packaging foods. FDA concludes that the available toxicological and exposure data for lead demonstrate that the use of lead solder to manufacture cans for packaging food may be injurious to the public health, particularly that of fetuses, infants, and children. This final regulation also responds to a citizen petition requesting that the agency require that warning labels be placed on food cans that contain lead solder.

DATES: *Effective:* December 27, 1995. Written objections and requests for a hearing by July 27, 1995. Compliance

date for affected products initially introduced or initially delivered for introduction into interstate commerce is December 27, 1995. Existing stocks of lead-soldered canned foods will be allowed to be offered for sale until June 27, 1996, so long as the level of lead in the food packaged in such cans is not such that the food may be rendered injurious to health.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3093.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1993 (58 FR 33860), FDA published a proposal to prohibit the use of lead solder to manufacture food cans. The proposal was in response to the agency's determination that: (1) The current daily dietary lead intakes of infants and children approach or may exceed the provisional total tolerable intake level (PTTIL) that the agency has established for lead for these population groups; (2) the use of lead solder in food cans adds lead to food which may render it injurious to health, particularly that of fetuses, infants, and children; and (3) lead solder is not required to manufacture food cans and can be avoided. Therefore, the agency proposed not to codify in its regulations the prior sanction for lead solder used in food cans but to prohibit this use.

In a notice published in the **Federal Register** of April 1, 1993 (58 FR 17233), the agency announced emergency action levels for lead in food packaged in lead-soldered cans. These action levels are an interim measure to protect infants and young children from adverse effects that could result from regular consumption of foods packaged in lead-soldered cans, pending completion of the rulemaking to prohibit the use of lead solder in food cans. After the 1-year period allowed for sale of existing stocks of lead-soldered canned foods, these emergency action levels will no longer be needed and will be considered as withdrawn by the agency.

This final rule amends the food additive regulations to prohibit the use of lead solder in cans to package food. In addition, with completion of this rulemaking, FDA is responding to a citizen petition requesting that the agency require warning labels on food

cans that contain lead solder, because the ban on the use of lead solder in food cans renders the labeling issue moot.

II. Discussion of Comments

In response to the notice of proposed rulemaking to prohibit the use of lead solder in food cans, FDA received eight comments. The comments were from a labor union, a State Government, an individual, two nonprofit public interest organizations, and three trade associations representing the can manufacturing industry, the food industry, and the Danish meat-canning industry.

One comment agreed that documentation clearly supports FDA's finding that a prior sanction exists for lead solder used in metal food packaging. All eight comments supported FDA's proposal to prohibit the use of lead solder in cans that are used to hold food. One comment submitted economic data on the cost to Danish meat canners of switching to other canning technologies. This comment is discussed in section IV. of this document. Other issues raised by the comments, and the agency's responses to them, are set forth below.

1. One comment stated that lead solder is incorrectly described in the proposed regulation as being " * * * used in the construction of the metal ends of food cans." The comment explained that, although lead solder was historically used to seal both the end and side seams of metal cans, current production of lead-soldered containers involves use of lead solder only to seal side seams of the container. The comment suggested that the regulation state that "Lead solders * * * are used in the construction of the side seams of food cans."

The agency agrees that the language in the regulation should be clarified. However, even though lead solder is currently used to seal only side seams of containers, FDA is prohibiting all uses of lead solder in food cans. Therefore, FDA is modifying the regulation to read: "Lead solders are alloys of metals that include lead and are used in the construction of metal food cans." This language clarification does not affect the intent or scope of the regulation.

2. One comment disagreed with language in the June 21, 1993, proposed rule, characterizing the agency's proposed action to ban the use of lead solder in food cans as a proposal to "revoke" the prior sanction for this use of lead solder. The comment contended that although §§ 181.1(b) and 181.5(c) (21 CFR 181.1(b) and 181.5(c)) provide that the agency may prohibit the use of

a prior-sanctioned ingredient if scientific data or information show that use of the ingredient may be injurious to health, the agency cannot "revoke" a prior sanction. The comment stated that a prior sanction for the use of a food ingredient is based solely on its recognized use prior to enactment of the Food Additives Amendment of 1958 (to the Federal Food, Drug, and Cosmetic Act (the act)), and that revocation of a prior sanction is inconsistent with the meaning and intent of the law.

FDA considers the comment to be making a semantic point that ultimately has no effect on the agency's action. As the comment recognizes, FDA's regulations in § 181.1(b) provide that if scientific data or information show that use of a prior-sanctioned food ingredient may be injurious to health, and thus is in violation of section 402 of the act (21 U.S.C. 342), FDA can prohibit use of the ingredient in food. If the agency prohibits use of a prior-sanctioned food ingredient, this action has the effect of revoking the prior sanction for that use of the ingredient.

Further, § 181.5(c) states that known prior sanctions for food ingredients shall be the subject of a regulation, and that this regulation may be revoked to prohibit use of the ingredient to prevent adulteration of food in violation of section 402 of the act. If a regulation for the prior-sanctioned use of a food ingredient is revoked to prevent such adulteration, the prior sanction for that use is in effect also revoked.

Thus, the agency believes that revocation of a prior-sanctioned use is consistent with the intent of the regulations and the act. To disagree with this conclusion is tantamount to saying that FDA does not have the authority to determine whether a food ingredient can be used safely. This is obviously not true.

3. One comment requested that the effective date for the ban on the introduction or delivery for introduction of lead-soldered canned foods into interstate commerce be extended to 24 months after publication of a final rule in the **Federal Register**. The comment requested the extension to allow conversion of the meat can soldering lines in Denmark to other canning technologies. The comment estimated that the conversion of the meat can lines would be completed by the end of 1995.

The effective date for banning the use of lead solder in food cans, that FDA proposed in the document published in the **Federal Register** of June 21, 1993 (58 FR 33860), was based on a recognition that it might take some time for the domestic and foreign food industries to convert their equipment.

However, the agency's primary concern in establishing an effective date for this action is the protection of the public health. As stated in the June 21, 1993, proposed rule, FDA has determined that there is a need to control dietary lead intake, especially for fetuses, infants, and children, because exposure to very low lead levels has been associated with adverse health effects. The current daily dietary lead intakes of infants and children approach or may exceed the PTTIL that the agency has established for lead for these population groups. (Lead levels that exceed the PTTIL are likely to result in adverse health effects.) The use of lead solder in food cans adds lead to food, and available toxicological and exposure data establish that the lead may render the food injurious to health and, therefore, adulterated under section 402(a)(1) of the act. Further, lead solder is not required to manufacture food cans, and therefore, its use is avoidable.

Over the years, the agency has expressed its concern about dietary exposure to lead resulting from the use of lead-soldered cans for food. In the 1970's, the agency worked with the evaporated milk industry, the infant food industry, and manufacturers of juices for infants to establish voluntary quality assurance programs to reduce the levels of lead in their canned products. These efforts were discussed in an advanced notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 31, 1979 (44 FR 51233). In this ANPRM, FDA also announced its intent to establish action levels for food packaged in lead-soldered cans. The agency's goal was to reduce the dietary lead intake resulting from use of lead-soldered food cans by at least 50 percent within 5 years.

FDA has been in direct contact with foreign countries, including Denmark, that might export food in lead-soldered cans to the United States. Beginning in mid-1990, the agency sent letters to over 65 nations, reminding U.S. trading partners that FDA has made efforts over the past two decades to reduce the levels of lead in the U.S. food supply, and that U.S. food manufacturers were voluntarily discontinuing the use of lead solder in cans for packaging food. The agency also said that it was concerned about dietary lead exposure from lead-soldered canned foods imported from other countries. The agency has also held numerous discussions at world forums over the past few years regarding the need to reduce dietary exposures to lead, particularly that resulting from use of lead-soldered cans for food.

At a meeting held on July 7, 1992, the Mexican Government informed FDA that its food industry intended to eliminate use of lead-soldered cans by October, 1992. (In a followup letter dated June 8, 1993, the agency was informed that 90 percent of Mexican can manufacturers do not use lead solder (Ref. 1).) In response to our letters of 1990 and 1991 sent to U.S. trading partners, Brazil projected that lead-soldered cans would not be used in that country by early 1991 (Ref. 2). Information received from Poland (Ref. 3) and Guatemala (Ref. 4) indicated that their food industries were intending to convert to nonlead packaging in 1992. The Hungarian Government estimated that no foods would be packaged in lead-soldered cans in its country by the end of 1993, at the latest (Ref. 5).

Thus, through cooperative programs with food industries, notices and proposed rules published in the **Federal Register**, letters to foreign nations, and discussions held at world forums, FDA has provided adequate notice of its concerns about the use of lead solder in cans used for food. In addition, U.S. food manufacturers have already eliminated use of lead solder in cans for food, and several foreign governments have stated that their food industries intended to discontinue use of lead-soldered cans by the end of 1993, at the latest. The agency therefore concludes that the effective date of 6 months after the publication of a final rule for the ban on the use of lead solder in food cans is achievable and equitable. The agency also notes that, given the date of publication of this final rule, the ban will not be effective any earlier than the beginning of 1996. This timeframe coincides with the time in which the comment predicted that conversion of the meat can lines in Denmark would be completed.

Based on the above considerations, in particular the need to protect the public health, the agency concludes that the effective date for the final rule prohibiting the use of lead solder in food cans from being introduced or delivered for introduction into interstate commerce should not be extended to 24 months after publication of a final rule in the **Federal Register**, as requested by the comment.

4. One comment from a trade association supported FDA's proposal to prohibit foods in lead-soldered cans from being introduced or delivered for introduction into interstate commerce 6 months after publication in the **Federal Register** of a final rule on this action and to allow existing stocks of lead-soldered canned foods to be offered for sale within 1 year of the date of

publication of the final rulemaking. The comment stated that if the 6-month effective date applies to initial introduction or initial delivery for introduction into interstate commerce, the proposed effective dates are equitable for both domestic and foreign food manufacturers.

The agency confirms that the 6-month effective date is applicable to initial introduction and initial delivery for introduction into interstate commerce of foods in lead-soldered cans. Based on this comment and the issues raised in addressing comment 3 above, the agency concludes that the ban on the initial introduction and initial delivery for introduction into interstate commerce of foods in lead-soldered cans should be effective 6 months after publication of a final rule in the **Federal Register**, and that existing stocks of lead-soldered canned foods should be allowed to be offered for sale within 1 year of the date of publication of the final rulemaking, so long as the level of lead in the food packaged in such cans is not such that the food may be rendered injurious to health. Guidance on the level of lead in food that may render the food injurious to health is provided by the emergency action levels, that were announced in the April 1, 1993, notice, of 80 micrograms per kilogram (80 parts per billion (ppb)) for lead in fruit beverages packed in lead-soldered cans and 250 ppb for all other foods packed in lead-soldered cans.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule published in the **Federal Register** of June 21, 1993. No new information or comments have been received that would affect the agency's previous determination that prohibiting the use of lead solder in food cans will not have a significant impact on the human environment, and that an environmental impact statement is not required.

IV. Economic Impact and Comment on the Economic Issues Raised in the June 21, 1993, Proposed Rule

FDA has examined the economic impacts of this final rule to amend the food additive regulations to prohibit the use of lead solder to manufacture cans that contain food, as required by Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives, and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96-354) requires analyzing options for regulatory relief for small businesses.

FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant impact on a substantial number of small businesses.

The June 21, 1993, proposed rule included an analysis of the economic impact of the proposed ban on the use of lead-soldered food cans under the previous Executive Order (E.O. 12291). FDA determined that this rule would result in little or no additional cost to domestic can manufacturers and food processors. In addition, the agency estimated that the one-time, upper-bound cost for foreign countries, that export lead-soldered canned foods to the United States, to convert to cans without lead solder would be from \$33 million to \$70 million. The total benefit gained from the reduction in blood lead levels resulting from the ban on the use of lead-soldered food cans was estimated to be \$80 million for the next 20 years (discounted at a 6 percent interest rate).

The agency received one comment on the June 21, 1993, proposed rule that supplied data on the cost to Danish meat canners of switching from lead-soldered cans to other canning technologies. The agency's evaluation of the data submitted is set forth below:

5. The comment from the Danish meat-canning industry estimated that the conversion of the meat-can soldering lines in Denmark to other canning technologies would cost approximately 30 million Danish kroner (approximately \$4.4 million using the exchange rate quoted in the *Washington Post* of November 24, 1993). As discussed in comment three above, this industry also requested that the effective date for the ban on the initial introduction or delivery for introduction of lead-soldered food cans into interstate commerce be extended to 24 months after publication of a final rule in the **Federal Register**. The comment stated that meat packaged in large cans is wrapped in a plastic bag inside the can, which would effectively inhibit lead migration into the meat.

FDA analyzed the economic impact of the request to extend the effective date for the ban on the use of lead-soldered food cans and determined that granting an extension to Danish canned meat exporters would not be necessary

because the effective date of the ban and the requested date coincide. Because FDA's estimate of the one-time, upper-bound cost for the conversion of canning lines in foreign countries was so broad (\$33 million to \$70 million), the cost information supplied by the Danish industry would not significantly alter the previous estimate.

V. Conclusions

FDA finds that a prior sanction exists for the use of lead solder in food cans. However, the available toxicological and exposure data on lead demonstrate that this use of lead solder may be injurious to the public health, particularly that of fetuses, infants, and children. Therefore, the agency is not codifying in its regulations the prior sanction for lead solder used in food cans and is instead amending its food additive regulations to prohibit this use of lead solder.

For clarification, FDA is modifying the language in proposed § 189.240(a) to read "Lead solders are alloys of metals that include lead and are used in the construction of metal food cans."

The ban on the initial introduction and initial delivery for introduction into interstate commerce of foods in lead-soldered cans will be effective 6 months after publication in the **Federal Register** of a final rule on this action. Existing stocks of lead-soldered canned foods will be allowed to be offered for sale within 1 year of the date of publication of the final rulemaking, so long as the level of lead in the food packaged in such cans is not such that the food may be rendered injurious to health.

FDA has now responded to a citizen petition (Docket No. 82P-0371/CP) requesting that the agency require warning labels on food cans that contain lead solder because the labeling issue will be moot with completion of this rulemaking.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 27, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and

analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Mercedes Juan (Secretariat of Health, Mexico) to Jane E. Henney (FDA), dated June 3, 1993.

2. Letter from Myrna Sabino (Secretariat of Health, Brazil) to Jerry A. Burke (FDA), dated August 9, 1990.

3. Letter from Kazimierz Karlowski (National Institute of Hygiene, Poland) to Jerry A. Burke (FDA), dated December 21, 1990.

4. Letter from Alberto Rodas Maltez (Alimentos Kern, Guatemala) to Economics Staff (FDA), dated April 24, 1991.

5. Letter from Judith Sohar (National Institute of Food-Hygiene, Hungary) to Jerry A. Burke (FDA), dated September 26, 1990.

List of Subjects in 21 CFR Part 189

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 189 is amended as follows:

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

1. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 189.240 is added to subpart C to read as follows:

§ 189.240 Lead solders.

(a) Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.

(b) Food packaged in any container that makes use of lead in can solder is deemed to be adulterated in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the **Federal Register** of June 27, 1995.

Dated: June 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-15593 Filed 6-26-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Xylazine Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Channele Pharmaceuticals Manufacturing Ltd. The ANADA provides for intravenous and intramuscular use of xylazine injection in horses and intramuscular use in *Cervidae* spp. to produce sedation accompanied by a shorter period of analgesia.

EFFECTIVE DATE: June 27, 1995.

FOR FURTHER INFORMATION CONTACT:

Sandra K. Woods, Center For Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

SUPPLEMENTARY INFORMATION: Channele Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland, filed ANADA 200-139 which provides for intravenous and intramuscular use of Chanazine® (100 milligrams/milliliter (mg/mL) Injectable (xylazine hydrochloride equivalent to 100 mg xylazine per mL) in horses and intramuscular use in *Cervidae* spp. (fallow deer, mule deer, Sika deer, white-tailed deer, and elk) to produce sedation accompanied by a shorter period of analgesia. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200-139 for Channele's Chanazine® (xylazine 100 mg/mL) Injectable is as a generic copy of Miles' NADA 047-956 for Rompun® (xylazine 100 mg/mL) Injectable. The ANADA is approved as of May 16, 1995, and the regulations are amended by revising 21 CFR 522.2662(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Channele Pharmaceuticals Manufacturing Ltd. has not previously been listed in the animal drug regulations as the sponsor of an approved application. At this time, 21 CFR 510.600(c) is amended to add entries for the firm.