§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

Paragraph 2004 Jet Routes

* * * * *

J–158 [Revised]

From Mina, NV, via Lucin, UT; Malad City, ID; Big Piney, WY; Muddy Mountain, WY; Rapid City, SD; to Aberdeen, SD.

* * * * *

Issued in Washington, DC, on December 1, 2005.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. 05–23758 Filed 12–7–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1994F–0153] (formerly Docket No. 94F–0153)

Food Additives Permitted for Direct Addition to Food for Human Consumption; Synthetic Fatty Alcohols

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of *n*-octanol (*n*-octyl alcohol) produced by a new manufacturing process, the hydrodimerization of 1,3-butadiene. This action is in response to a petition filed by Kuraray International Corp.

DATES: This rule is effective December 8, 2005. Submit written or electronic objections and requests for a hearing by January 9, 2006. See section VI of this document for information on the filing of objections. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in new § 172.864(a)(3) (21 CFR 172.864(a)(3)) as of December 8, 2005.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 1994F–0153, by any of the following methods:

Electronic Submissions

Submit electronic submissions in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of submissions, FDA is no longer accepting submissions sent to the agency by e-mail. FDA encourages you to continue to send electronic submissions by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this section of this document.

Instructions: All submissions received must include the agency name and docket number and regulatory information number (RIN) (if a RIN number has been assigned) for this rulemaking. All objections received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1272.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of May 26, 1994 (59 FR 27281), FDA announced that a food additive petition (FAP 4A4419) had been filed by Kuraray International Corp., c/o 1001 G St. NW., Washington, DC 20001. The petition proposed to amend the food additive regulations in § 172.864 *Synthetic fatty alcohols* (21 CFR 172.864) to provide for the safe use of *n*-octanol produced by a new manufacturing process, the hydrodimerization of 1,3-butadiene. Subsequently, Kuraray America, Inc., notified the agency of the merging of Kuraray International Corp., into Kuraray America, Inc., and the transfer of ownership of the petition (FAP 4A4419) to Kuraray America, Inc.

n-Octanol (*n*-octyl alcohol) synthesized by the proposed manufacturing process is intended for use in the same manner as *n*-octanol prepared by other manufacturing processes under § 172.864.

In evaluating the safety of *n*-octanol synthesized by the proposed manufacturing process, FDA has reviewed the safety of the additive and the chemical impurities that may be present in it resulting from its manufacturing process. Although *n*-octanol has not been shown to cause cancer, it may contain minute amounts of residual precursor as an impurity resulting from its method of production. In particular, *n*-octanol may contain traces of the precursor, 1,3-butadiene, which has been shown to cause cancer in test animals. Residual amounts of reactants and their impurities are commonly found as contaminants of chemical products, including food additives.

II. Determination of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as a ''reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (section 409(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause

cancer, but contains a carcinogenic impurity, the additive is evaluated properly under the general safety standard using risk assessment procedures to determine whether there is reasonable certainty that no harm will result from the intended use of the additive (*Scott*v. *FDA, 728 F.2d 322 (6th Cir. 1984)*).

In evaluating the safety of a food additive, FDA customarily reviews the available data on each relevant chemical impurity to determine whether the chemical induces tumors in animals or humans. If FDA concludes that the chemical impurity causes cancer in animals or humans, the agency calculates the unit cancer risk for the chemical and the upper-bound limit of lifetime human cancer risk from the chemical's presence in the additive.

In some instances, the available data and information may not allow the agency to determine whether a particular chemical impurity in a food additive is a carcinogen via ingestion. However, the available data may suggest, but not establish definitively, that the impurity poses a human cancer risk via this route. In such circumstances, the agency may perform a risk assessment based upon the available data and the assumption that the impurity is carcinogenic via ingestion. This approach permits the agency to determine whether there is a reasonable certainty that no harm will result from the petitioned use of the food additive, even though the carcinogenic status of the impurity is not clearly established. FDA followed this approach to determine whether there is a reasonable certainty that no harm will result from the food additive use of *n*-octanol synthesized by hydrodimerization of 1,3-butadiene. In doing so, FDA assumed that 1,3-butadiene, an impurity in the additive, would also be carcinogenic when administered by ingestion.

A. Evaluation of the Petitioned Use of the Additive Produced by the New Manufacturing Process

n-Octanol produced by the proposed manufacturing process, the hydrodimerization of 1,3-butadiene, is intended to be used in the same manner as currently permitted synthetic and naturally derived *n*-octanol. Therefore, FDA concludes that the proposed amendment to the regulation providing for the petitioned manufacturing process for *n*-octanol will not result in a change in the daily intake of the additive *n*-octanol because no new uses are proposed. Thus, the only new issue is human exposure to 1,3-butadiene from food containing *n*-octanol produced by the new manufacturing process.

FDA has evaluated the safety of *n*-octanol produced by the new manufacturing process, under the general safety standard, and concludes that the use of the resulting additive is safe. In reaching this conclusion, FDA reviewed relevant toxicological data on 1,3-butadiene and used risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by levels that may be present in the petitioned additive.

The risk evaluation of 1,3-butadiene has two aspects: (1) Assessment of exposure to 1,3-butadiene from the petitioned use of *n*-octanol produced by the new manufacturing process and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

B. 1,3-Butadiene

In one long-term inhalation study in mice, 1,3-butadiene has been reported to induce a variety of tumors, including in the hematopoietic system, heart, lung, forestomach, liver, Harderian gland, brain, and kidney in both sexes and tumors of the ovaries and mammary gland in female mice (Ref. 1). 1,3-Butadiene also has been reported to induce tumors of the pancreas and testis in male rats and tumors of the uterus, mammary gland, and thyroid in female rats in another long-term inhalation study (Refs. 2 and 3). FDA does not believe, however, that these inhalation studies are necessarily determinative of the carcinogenic potential of 1,3-butadiene when administered orally, the route of human exposure to food additives.

No long-term studies are available in which 1,3-butadiene was administered to test animals orally. Therefore, the agency has performed a carcinogenicity risk assessment for 1,3-butadiene based on the assumption that 1,3-butadiene would induce tumors in animals and humans if administered orally and that its potency by the oral route of exposure would be no greater than its potency by the inhalation route of exposure (the predominant route of exposure). In this risk assessment the agency utilized data on female mice from an inhalation study of 1,3-butadiene to calculate a unit cancer risk of 1.4 (milligrams per kilograms (kg) body weight per day)$^{-1}$ for 1,3-butadiene (Ref. 4).

1,3-Butadiene was not detected in the product. However, based on the limit of detection, FDA has estimated the exposure to 1,3-butadiene from the petitioned use of the subject additive would not exceed 0.63 parts per trillion in the daily diet (3 kg), or 1.9 nanograms per person per day (Refs. 5 and 6). Based on this estimate and the assumption that 1,3-butadiene would induce tumors with the same potency in an oral study as it did in the mouse inhalation study, FDA estimates that the upper-bound limit of lifetime human risk from butadiene exposure as a result of the petitioned used of the subject additive would be 4.4×10^{-8} (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,3-butadiene is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to 1,3-butadiene would result from the petitioned use of the additive.

C. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of 1,3-butadiene present as an impurity in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) The agency would not expect 1,3-butadiene to become a component of food at other than extremely low levels because of its volatility and the low levels at which 1,3-butadiene (below detection limit) may be expected to remain as an impurity following production and purification of the additive and (2) the upper-bound limit of lifetime human risk from exposure to 1,3-butadiene is very low, 4.4×10^{-8}.

III. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive produced by the new manufacturing process is safe, and, therefore, the regulations in § 172.864 should be amended as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this final rule. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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 are to be submitted and are to 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

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

1. ''Toxicology and Carcinogenesis Studies of 1,3-Butadiene (CAS No. 106–99–0) in B6C3F1 Mice (Inhalation Studies),'' National Toxicology Program, Technical Report Series, No. 434.

2. Owen, P.E. et al., ''Inhalation Toxicity Studies with 1,3-Butadiene. 3 Two Year Toxicity/Carcinogenicity Studies in Rats,'' *American Industrial Hygiene Association Journal*, 48: 407–413, 1987.

3. Owen, P.E. and J.R. Glaister, ''Inhalation Toxicity and Carcinogenicity Study of 1,3-Butadiene in Sprague-Dawley Rats,'' *Environmental Health Perspectives*, 86: 19–25, 1990.

4. Memorandum dated February 23, 2001, from the Division of Product Policy, Scientific Support Branch to the Division of Product Policy, Regulatory Policy Branch, ''Food Additive Petition 4A4419—Kuraray America Inc. (formerly Kuraray International Corporation)/Keller & Heckman. *n*-Octanol, a currently cleared synthetic fatty alcohol produced by a new manufacturing process, for use as an ingredient in food. Submissions dated 4–7–1994 and 4–12–1994.''

5. Memorandum dated May 3, 1994, from the Chemistry Review Branch to the Indirect Additives Branch, ''FAP 4A4419 (MATS #763, M2.1.1)—Kuraray International Corporation. Submission dated 4–7–94. Request of 4–20–94 from Indirect Additives Branch: Estimated exposure to 1,3-butadiene from the use of synthetic *n*-octanol.''

6. Memorandum dated July 26, 1994, from the Chemistry Review Branch to the Indirect Additives Branch, ''FAP 4A4419 (MATS #763, M2.1)—Kuraray International Corporation/Keller & Heckman. Submissions dated 4–7–94 and 4–12–94. *n*-Octanol via a new manufacturing process.''

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.864 is amended by adding paragraph (a)(3) to read as follows:

§ 172.864 Synthetic fatty alcohols.

* * * * *

(a) * * *

(3) n-Octyl; manufactured by the hydrodimerization of 1,3-butadiene, followed by catalytic hydrogenation of the resulting dienol, and distillation to produce *n*-octyl alcohol with a minimum purity of 99 percent. The analytical method for *n*-octyl alcohol entitled ''Test Method [Normal-octanol]'' dated October 2003, and printed by Kuraray Co., Ltd., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

* * * * *

Dated: November 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23745 Filed 12–7–05; 8:45 am]

BILLING CODE 4160–01–S

HOUSING AND URBAN DEVELOPMENT

24 CFR Part 941

Public Housing Development

CFR Correction

In Title 24 of the Code of Federal Regulations, parts 700 to 1699, revised as of April 1, 2005, on page 381, § 941.207 is corrected by removing the parenthetical statement at the end of the section.

[FR Doc. 05–55518 Filed 12–7–05; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9232]

RIN 1545–BD33

Guidance on Passive Foreign Investment Company (PFIC) Purging Elections

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulation.

SUMMARY: This document contains temporary regulations that provide certain elections for taxpayers that