respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number associated with this collection is 2120–0691. The request was approved by OMB without change and expires on November 30, 2007.

Additionally, the Final Rule was published without amendment numbers. This notice adds those amendment numbers as shown in the heading.

49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 46105, grants authority to the Administrator to publish this notice. The final rule (FR 69 39292) is effective immediately.

Issued in Washington, DC, on June 15, 2005.

Anthony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 05–12239 Filed 6–17–05; 11:35 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2002F–0160]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying requests that it has received for a hearing on the final rule that amended the food additive regulations authorizing the use of vitamin D_3 as a nutrient supplement in calcium-fortified fruit juices and fruit drinks, excluding fruit juices and fruit juice drinks specially formulated or processed for infants, at levels not to exceed 100 International Units (IU) per serving. (In the final rule, FDA used the term ''fruit drink;'' however, the common or usual name of the product is ''fruit juice drink.'' Therefore, FDA is replacing the term ''fruit drink'' with ''fruit juice drink.'') In response to one of the objections, FDA is amending the vitamin D_3 regulation to replace the current 100 IU per serving limits on the vitamin D_3 fortification of fruit juices and fruit juice drinks with limits of 100 IU per 240 milliliters (mL). This document also corrects three errors that appeared in the codified portion of the vitamin D_3 final rule.

DATES: This rule is effective June 22, 2005. Submit written or electronic objections and requests for a hearing by July 22, 2005. See section IX of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2002F–0160, by any of the following methods:

- 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.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2002F–0160 in the subject line of your e-mail message.
- 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.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will 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 objections 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: Judith L. Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of April 25, 2002 (67 FR 20533), FDA published a notice announcing the filing of a food additive petition (FAP 2A4734) by the Minute Maid Co. (Minute Maid), to amend the food additive regulations in part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of vitamin D_3 as a nutrient supplement in calcium-fortified fruit juices and fruit juice drinks. In response to FAP 2A4734, in the **Federal Register** of February 27, 2003 (68 FR 9000), FDA issued a final rule permitting the safe use of vitamin D_3 as a nutrient supplement in calcium-fortified fruit juices and fruit juice drinks[1], excluding fruit juices and fruit juice drinks specially formulated or processed for infants, at levels not to exceed 100 IU per serving. This regulation was codified in § 172.380. FDA based its decision on data contained in the petition and in its files.

The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date, by March 31, 2003. FDA received several submissions within the 30-day objection period. Some of the submissions sought revocation of the final rule and requested a hearing. In response to one of the objections received during the 30-day objection period, FDA is amending the food additive regulation to replace those portions of the vitamin D_3 regulation that prescribe limits on vitamin D_3 fortification of fruit juices and fruit juice drinks of 100 IU per serving with limits of 100 IU per 240 mL. This document also corrects three errors that appeared in the codified portion of the vitamin D_3 final rule.

II. Objections and Requests for a Hearing

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(f)), provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order ''* * * deemed objectionable, stating reasonable grounds therefore, and requesting a public hearing [based] upon such objections.'' FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing.

Under 21 CFR 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a) each

[1] In the final rule (68 FR 9000), FDA used the term ''fruit drink.'' In 21 CFR 102.33, the common or usual name of the product is ''fruit juice drink.'' To be consistent with § 102.33, FDA is replacing the term ''fruit drink'' with ''fruit juice drink'' in § 172.380(d) and elsewhere in this document.

objection must: (1) Be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) specifically state the provision of the regulation or proposed order on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; and (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought).

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. denied*, 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information (see *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971)). In other words, a hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue.'' (*Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles ''self-evidently'' ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote:

> The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.

Retail Clerks Union, Local 1401 v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation*, supra at 215–220. See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968), *cert. denied*, 393 U.S. 1093 (1969).)

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Hearing Requests

Objections to the vitamin D_3 final rule can be grouped into five broad categories that include the following: (1) Inconsistencies between the codified language and the intent of the petitioner; (2) the use of an animal-derived food additive; (3) the effect on milk consumption and obesity; (4) hypercalcemia concerns; and (5) inconsistency with FDA's fortification policy[2]. FDA addresses each of the objections listed in this document, as well as the evidence and information filed in support of each. If a hearing was requested, we compared each objection and the information submitted to support it to the standards for granting a hearing in § 12.24.

A. Inconsistencies Between Codified Language and Intent of Petitioner

One submission, from Unilever United States, Inc. (Unilever), objected to vitamin D_3 fortification limits based on serving size rather than reference amount customarily consumed (RACC). The RACC, a fixed amount established by regulation § 101.12 (21 CFR 101.12), is to be used as the basis for determining serving sizes for specific products. Serving sizes, however, may vary depending on how a product is packaged (§ 101.9(b)).

Unilever pointed out that the fortification levels based on serving size, rather than RACC, will result in levels of vitamin D_3 in fortified fruit juices and fruit juice drinks that are inconsistent, on a per-mL basis, with the levels of vitamin D_3 in milk and also with the levels of vitamin D_3 in differently sized containers of fortified fruit juices and fruit juice drinks. According to Unilever, this would not be consistent with the intent of the petition that initiated the rulemaking and also would be confusing to consumers. Unilever stated that the intent of the petition is achieved when the fruit juice and fruit juice drinks are fortified with vitamin

[2] FDA received several letters within the 30-day objection period that expressed general opposition to the use of vitamin D_3 in fruit juices and fruit juice drinks. These letters identified no substantive issue to which the agency can respond, and did not request a hearing. These submissions will not be discussed further.

D_3 at 100 IU per RACC value of 240 mL, rather than 100 IU per serving. As explained in the preamble to the vitamin D_3 final rule (68 FR 9000), the RACC for fruit juices and fruit juice drinks intended for the general population is 240 mL.

FDA has reviewed the issues raised by Unilever. FDA determined that the petitioned uses of vitamin D_3 are safe based on a fortification level of 100 IU of vitamin D_3 per RACC (240 mL) of fruit juice and fruit juice drinks and had intended to establish such a limit but inappropriately used the term ''serving'' as a synonym for RACC. There will be no adverse effect on the public health if the term ''serving'' is replaced with the RACC value ''240 mL.'' Therefore, the agency concludes that replacing ''100 IU per serving'' with ''100 IU per 240 mL'' is consistent with the record for this petition as evidenced by both the petitioner's intentions and FDA's safety evaluation of FAP 2A4734. For the foregoing reasons, under § 12.26, FDA is replacing the term ''serving'' with ''240 mL'' in § 172.380(c) and (d). As discussed in section VI of this document, § 172.380 limits the vitamin D_3 fortification of fruit juices to those with greater than or equal to 33 percent of the Reference Daily Intake (RDI) of calcium per RACC and, for fruit juice drinks, to those with greater than or equal to 10 percent of the RDI of calcium per *RACC* (emphasis added). To be consistent with specifying the vitamin D_3 fortification limits in terms of the RACC value of 240 mL, FDA also is replacing the terms ''Reference Amount Customarily Consumed'' and ''RACC'' as used in § 172.380(c) and (d) with ''240 mL.''

B. Animal-Derived Food Additive

FDA received several letters from vegetarians and vegans expressing opposition to the rule because vitamin D_3 can be derived from fish liver oil. Some of these objectors stated that, because vitamin D_3 may be derived from an animal source, its addition to fruit juices and fruit juice drinks would limit their food choices. Others objected to the rule because listing the ingredient as vitamin D_3 will not make it apparent that the vitamin D_3-fortified fruit juices and fruit juice drinks may contain an animal product. One objector requested that FDA require a label statement alerting consumers that the additive is derived from an animal product.

The final rule permits the use of vitamin D_3 only in calcium-fortified fruit juices and fruit juice drinks. Data from the U.S. Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals conducted from 1994 through 1996 indicate that only a small fraction (approximately less than 5 percent) of the fruit juices and fruit juice drinks available to consumers is fortified with calcium. More recent data, however, indicate that the percentage of calcium-fortified fruit juices and fruit juice drinks could be somewhat higher (approximately 20 percent to 30 percent market share) due to the increasing demand and marketability of calcium-fortified products (Ref. 1). Nevertheless, there remains a relatively large percentage of fruit juices and fruit juice drinks that will not be fortified with vitamin D_3. Additionally, all food ingredients are required to be listed on the label of the product; therefore, consumers can choose to avoid a product that contains a specific ingredient.

To justify a revocation of the food additive regulation, an objector must establish that FDA failed to conduct a fair evaluation of the evidence in the record and, thus, erroneously concluded that the use is safe (see section 409(c)(3) of the act (21 U.S.C. 348(c)(3)). The objections summarized previously in this document cited no data or information relevant to FDA's safety evaluation. Because these objections cited no data or information to demonstrate that the use of an animal-derived food additive is not safe, FDA has concluded that there is no basis to modify or revoke the food additive regulation for vitamin D_3.

Some of the objections summarized previously in this document requested a hearing on the subject but did not point to any specific aspect of the rule that they sought to challenge. Because no evidence was submitted to support these objections, they raise no factual issue for resolution and, therefore, do not justify a hearing (§ 12.24(b)(1)).

C. Effect on Milk Consumption and Obesity

FDA received objections from the American Academy of Pediatrics (AAP), the National Dairy Council (NDC) and the University of California at Davis, Department of Nutrition (UC-Davis), that assert FDA did not consider the effect that vitamin D_3 fortification of fruit juices and fruit juice drinks would have on consumption of these beverages. They were concerned that vitamin D_3 fortification of fruit juices and fruit juice drinks would promote increased intake of these drinks, and that higher intakes of these beverages may be a contributing factor in childhood obesity. These objectors also expressed concern that fortified fruit juices and fruit juice drinks would likely result in decreased consumption of milk and the associated vitamins and minerals in that food. The NDC expressed a concern that fortification of fruit juice drinks with vitamin D is inconsistent with Dietary Guidelines for Americans and the USDA Food Guide Pyramid because these guidelines recommend limiting the intake of sugar from foods and beverages, including fruit juice drinks. The NDC contends that the vitamin D_3 rule should be stayed until the issues they raised have been resolved. The AAP requested a hearing on its objections.

As a basis for their objections, AAP and UC-Davis cited a report from the National Institute of Child Health and Human Development that reviewed evidence supporting a role for dietary calcium and, possibly, dairy intake in the regulation of body adiposity. The report concluded that the available, limited, data support a conclusion that dietary calcium *may* (emphasis added) play a role in body weight regulation and lend support to the hypothesis that increasing dietary calcium or dairy intake may be associated with reduced incidence of adiposity. The report recommended that well-designed, population-based clinical trials be carried out to determine the actual mechanism involved.

The subject of the vitamin D_3 rulemaking is whether the use of the additive in fruit juices and fruit juice drinks, within the limits provided, is safe. As stated in § 12.24(b)(1), a hearing will not be granted on issues of policy or law. Therefore, FDA is denying AAP's request for a hearing. Additionally, FDA has concluded that there is no basis in NDC's objections to stay the food additive regulation for vitamin D_3.

Furthermore, FDA notes that objectors did not submit any evidence that demonstrates that vitamin D_3 fortification of fruit juices and fruit juice drinks will lead to an increased consumption of these beverages or that such fortification will lead to a decrease in milk consumption. Additionally, these objectors also provided no evidence that demonstrates that there is a link between increased fruit juice and fruit juice drink consumption and childhood obesity.

D. Hypercalcemia

Another issue raised by AAP was that FDA did not evaluate the potential effects of exposure to calcium from vitamin D_3 fortification of calcium-fortified fruit juices and fruit juice drinks. They stated that, while the potential for adverse effects from excess vitamin D or calcium is minimal, there are not sufficient consumption data

available for assessing children's risk of higher combined intakes of these two nutrients. The AAP asserts that individuals with renal disease might be at special risk due to hypercalcemia associated with hypervitaminosis D.

FDA explicitly considered the issue of hypercalcemia, as reflected in the record. In addressing the issue of hypercalcemia, the agency relied upon upper tolerable daily intake levels (ULs) for vitamin D established by the Institute of Medicine (IOM) in 1997, as well as publications on vitamin D that appeared in the literature subsequent to the 1997 IOM report. IOM established the ULs based on multiple factors, including the significant dose-dependent increases in serum calcium concentration followed by daily supplementation of vitamin D, sensitive individuals, short duration of available studies, and limited sample sizes. Studies published after the 1997 IOM report support that vitamin D supplementation is without adverse effects at the IOM UL of 2,000 IU for adults, including elderly women and adults with osteoporosis. The IOM stated that the adult UL is appropriate for children based on increased rates of bone formation in children and because no data indicated difficulties in renal clearance by 1 year of age. No new reported studies on the effects of vitamin D supplementation in children have been published since 1997.

The agency agrees that hypercalcemia could result from excessive consumption of vitamin D-fortified foods and was the primary basis for the 1985 final rule affirming the use of vitamin D as GRAS with specific limitations as a direct human food ingredient (50 FR 30149, July 24, 1985). In the final rule, FDA concluded that ''* * * a petition for new food uses of vitamin D is necessary so that the agency can assure that total dietary exposure will not increase significantly, and that any increase in exposure is safe.'' As with any food additive, FDA will re-evaluate the safety of vitamin D-fortification of foods as new data become available.

The agency recognizes that hypercalcemia may accelerate the progression of renal disease. While there are individuals that must carefully monitor or limit the amount of calcium intake for medical reasons, both vitamin D and calcium must be declared on the label if they are added to foods. Listing these on the food label makes it possible for people to avoid these ingredients, if necessary. The AAP has not pointed to any evidence that supports that FDA failed to consider potential safety effects of combined exposure to vitamin D and calcium.

E. Inconsistency With FDA's Fortification Policy

In its objections, NDC questions whether the fortification of fruit juices and fruit juice drinks is consistent with the principles in § 104.20(b)(1) (21 CFR 104.20(b)(1)). Section 104.20(b)(1) states that the nutrients listed in § 104.20(d)(3) may be appropriately added to a food to correct a dietary insufficiency recognized by the scientific community if there is sufficient information available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients.

FDA's fortification policy is intended to provide a consistent set of guidelines to be followed when nutrients are added to foods. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles. The policy does not prohibit the addition of nutrients to fruit juices and fruit juice drinks, or to any foods, as long as the proposed use of the additive is safe. The petitioner provided sufficient information for FDA to determine that the use of vitamin D_3 at the petitioned level in calcium-fortified fruit juices and fruit juice drinks is safe. The NDC cited no data or information to suggest that the intended use is not safe.

Moreover, in its submission, the petitioner provided a number of recent publications that identified clinical findings of vitamin D insufficiency and, in some cases, vitamin D deficiency, in several population groups (e.g., the elderly, toddlers, vegetarians, and young men and women during the winter months). Also, as evidence that calcium-fortified fruit juices and fruit juice drinks are suitable vehicles for vitamin D_3, the petitioner provided results of a clinical study that confirmed the bioavailability of vitamin D_3 in juice.

V. Summary and Conclusions

Section 409 of the act requires that a food additive be shown to be safe prior to marketing. Under 21 CFR 170.3(i), a food additive is ''safe'' if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the final rule approving vitamin D_3, FDA concluded that the data presented by the petitioner to establish safety of the additive demonstrate that vitamin D_3 is safe for its intended use in calcium-fortified fruit juices and fruit juice drinks.

The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Once FDA makes a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into questions FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

Only one objection contained evidence to support a genuine and substantial issue of fact. It should be noted that this objection does not call into question FDA's safety evaluation; it merely addresses an inconsistency between the petitioner's intent and the codified portion of the regulation. As a result of the objection, FDA is amending § 172.380 to replace those portions of the vitamin D_3 regulation that prescribe limits on the vitamin D_3 fortification of fruit juices and fruit juice drinks of 100 IU per serving with limits of 100 IU per 240 mL and to replace the terms ''Reference Amount Customarily Consumed'' and ''RACC'' as used in the regulation with ''240mL.''

VI. FDA's Corrections to the Final Rule (§ 172.380)

In addition to the issues raised by Unilever, FDA discovered three errors in the codified portion of the vitamin D_3 final rule. This document corrects these errors. Section 172.380(c) and (d) prescribes limits on the minimum levels of calcium fortification of fruit juice and fruit juice drinks with added vitamin D_3. In section B of the petition (Use and Purpose) (FAP 2A4734), Minute Maid stated that the proposed use was ''intended for use at levels currently approved for vitamin D-fortified milk, [s]pecifically, 100% fruit juice products fortified with ≥33% of the Recommended Daily Intake (RDI) of calcium per Reference Amount Customarily Consumed (RACC), and juice and juice drinks fortified with ≥10% of the RDI of calcium per RACC, are intended to be fortified with 100 IU (2.5 μg) vitamin D_3 per RACC.'' In Section F of the petition (Proposed Food Additive Regulation) (FAP 2A4734), however, the regulation mistakenly prescribed limits of calcium fortification of fruit juice and fruit juice drinks at ''greater than 33%'' and ''greater than 10%,'' respectively. In the codified section of the final rule, FDA listed the limitations on calcium fortification as ''greater than,'' rather than the petitioner's intention of ''greater than or equal to'' these percentages. FDA is changing the language in § 172.380(c) and (d) to ''greater than or equal to.'' Additionally, in its proposed food additive regulation, the petitioner used the term ''Recommended Daily Intake'' to describe the levels of calcium in fruit juices and fruit juice drinks. The correct

term is ''Reference Daily Intake.'' Reference Daily Intakes are values established by FDA for use in nutrition labeling. Most RDIs are based on the National Academy of Science's Recommended Daily Allowances. In the final rule, FDA inadvertently used the term ''recommended'' instead of ''reference'' to describe daily intake. Therefore, FDA is replacing the term ''Recommended Daily Intake'' in § 172.380(c) and (d) with ''Reference Daily Intake.'' Finally, in § 172.380(d), FDA used the term ''fruit drink.'' Under § 102.33 (21 CFR 102.33), the common or usual name of the product is fruit juice drink. To be consistent with § 102.33, FDA is replacing the term ''fruit drink'' with ''fruit juice drink'' in § 172.380(d).

VII. Environmental Effects

When FAP 2A4734 was filed, it contained a claim of categorical exclusion under 21 CFR 25.32(k). The agency reviewed this claim and found it to be warranted for the petitioned action. As a result, the agency stated in the notice of filing for FAP 2A4734 that neither an environmental assessment nor an environmental impact statement was required. The agency has concluded that the modifications to the regulation in response to the objections as well as the corrections that are being made to the regulation by this document will not change the agency's previous determination that the categorical exclusion in 25.32(k) is warranted.

VIII. 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.

IX. Objections

Any person who will be adversely affected by this amendment to the regulation may at any time 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 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following reference has 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. Memorandum from Folmer, Division of Petition Review, Chemistry Review Group, to Kidwell, Division of Petition Review, June 19, 2003.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

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

■ 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 to read as follows:

■ 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 172.380 is amended by revising the introductory text and paragraphs (c) and (d) to read as follows:

§ 172.380 Vitamin D_3.

Vitamin D_3 may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

* * * * *

(c) Vitamin D_3 may be added, at levels not to exceed 100 International Units (IU) per 240 milliliters (mL) to 100 percent fruit juices, as defined under § 170.3(n)(35) of this chapter, excluding fruit juices that are specially formulated or processed for infants, that are fortified with greater than or equal to 33 percent of the Reference Daily Intake (RDI) of calcium per 240 mL.

(d) Vitamin D_3 may be added, at levels not to exceed 100 IU per 240 mL to fruit juice drinks, as defined under § 170.3(n)(35) of this chapter, excluding fruit juice drinks that are specially formulated or processed for infants, that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL.

Dated: June 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12322 Filed 6–21–05; 8:45 am]

BILLING CODE 4160–01–S

NATIONAL CRIME PREVENTION AND PRIVACY COMPACT COUNCIL

28 CFR Part 901

[NCPPC 110]

Fingerprint Submission Requirements

AGENCY: National Crime Prevention and Privacy Compact Council.

ACTION: Final rule.

SUMMARY: The Compact Council, established pursuant to the National Crime Prevention and Privacy Compact (Compact) Act of 1998, is finalizing a rule amending part 901, which codified the Compact Council's interpretation of the Compact's fingerprint-submission requirements as it relates to the use of the Interstate Identification Index (III) for noncriminal justice record checks during an emergency situation when the health and safety of a specified group may be endangered.

DATES: *Effective Date:* This final rule is effective on June 22, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Donna M. Uzzell, Compact Council Chairman, P.O. Box 1489, Tallahassee, FL 32302, telephone number (850) 410–7100.

SUPPLEMENTARY INFORMATION: This document finalizes the Compact Council's proposed amendments to part 901 published in the **Federal Register** on December 5, 2003, (68 FR 67991). The Compact Council received no written comments on the proposed amendments and is finalizing the amended rule as proposed except for minor edits and clarifications.

Background

The Compact provides that ''Subjects fingerprints or other approved forms of positive identification shall be submitted with all requests for criminal history record checks for noncriminal justice purposes.'' *See* 42 U.S.C. 14616, Article V(a). The Compact Council recognizes the extreme reliability of fingerprint-based identifications and requires that fingerprints be submitted contemporaneously with search