

III data also show that, when vitamin D is taken as a dietary supplement, the most frequent level is 400 IU/day. The petitioner provided results from two Gallup polls that concluded that consumers of vitamin D₃-fortified fruit juices and fruit drinks also are likely to take supplemental sources of vitamin D. As a conservative estimate of intake of vitamin D from dietary supplements and food uses, the petitioner assumed that all consumers of fruit juices and juice drinks would take dietary supplements containing 400 IU of vitamin D. They then added this value to the mean and 90th percentile intake estimates from current and proposed food uses. For consumers of fruit juices and juice drinks 2 years of age and older, mean and 90th percentile dietary intake estimates from current and proposed food uses and dietary supplements were 706 IU/p/d and 919 IU/p/d, respectively.

Although the petitioner has notified FDA that it does not intend to fortify fruit juices and juice drinks specially formulated or processed for infants with vitamin D₃, the petitioner provided intake estimates for breastfed and non-breastfed infants, 0 to 6 months of age and 7 to 12 months of age. These estimates assumed that all fruit juices and juice drinks, including those specially formulated or processed for infants, would be fortified with vitamin D₃. Of these four infant population groups, intake estimates were the highest for non-breastfed infants, 0 to 6 months of age. For non-breastfed infants, 0 to 6 months of age, mean and 90th percentile dietary intake from current and proposed food uses were 443 IU/p/d and 663 IU/p/d, respectively. When dietary supplements were considered in the estimates for these consumers, mean and 90th percentile intakes were 843 IU/p/d and 1,063 IU/p/d, respectively. Intake estimates for the other infant population groups were below the UL for infants of 1,000 IU/day.

Due to the relatively small sample size of infants consuming fruit juices and juice drinks, the agency does not consider the intake estimates presented by the petitioner to be statistically robust enough to make a quantitative safety assessment. For example, for infants 0 to 6 months of age, non-breastfed, intake estimates were based on data from 49 consumers of fruit juice or juice drinks; for infants, 0 to 6 months, breastfed, 16 consumers; infants, 7 to 12 months, non-breastfed, 75 consumers; and infants, 7 to 12 months, breastfed, 9 consumers. Intake estimates from these populations are not considered to be statistically robust

when compared, for example, to the numbers of consumers in the sample populations for children 4 to 8 years of age (1,194 consumers) and 9 to 13 years of age (717 consumers).

Because a quantitative safety assessment cannot be made with the available data, we consider it appropriate to exclude fruit juices and juice drinks specially formulated or processed for infants (ages 0 to 12 months) from the proposed use of vitamin D₃. The agency recognizes that some infants may consume fruit juices and juice drinks that are not specially formulated or processed for infants (Ref. 3); however, fruit juices and juice drinks are not major components of the diets of infants. Further, in a May 2001 policy statement, the American Academy of Pediatrics recommended that fruit juice should not be given to infants before 6 months of age (Ref. 4).

C. Safety Assessment

The petitioner submitted over 80 published articles to support the safety of the proposed use of vitamin D₃ in calcium-fortified fruit juices and juice drinks. These articles included most of the references considered by IOM in its evaluation and all of the critical references that were the basis for the UL. The petitioner also submitted publications on vitamin D that appeared in the literature subsequent to the 1997 IOM report. New information since 1997 supports that vitamin D intake is without adverse effects at the IOM UL for adults (Ref. 5). No new studies in children on the effects of vitamin D intake have been published since 1997.

We considered the UL established by IOM for children (ages 1 year and older) and adults relative to the intake estimates provided by the petitioner as the primary basis for assessing the safety of the proposed use of vitamin D₃ in calcium-fortified fruit juices and juice drinks. For all population groups of children and adults evaluated, mean and 90th percentile intake estimates from current and proposed food uses of vitamin D are well below the IOM UL of 2,000 IU/p/day. Additionally, when dietary supplements are included in the calculations, intake estimates remain below the UL. Because the EDI of vitamin D from all sources is less than the UL, the agency believes that dietary exposure of vitamin D₃ from its use as a nutrient supplement in calcium-fortified fruit juices and juice drinks, excluding juices and juice drinks specially formulated or processed for infants, will not pose a safety concern (Ref. 5).

III. Conclusion

Based on all data relevant to vitamin D reviewed by the agency, FDA concludes that there is a reasonable certainty that no harm will result from the use of vitamin D₃ as a nutrient supplement at the levels specified in calcium-fortified fruit juices and juice drinks, excluding fruit juices and juice drinks specially formulated or processed for infants. Thus, vitamin D₃ is safe for its proposed use and the agency concludes that the food additive regulations should be amended as set forth in this document. To ensure that only food grade vitamin D₃ is used in food, the additive must meet the specifications of the *Food Chemicals Codex*, 4th ed.

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 listed previously. 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 Effects

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 2A4734 (67 FR 20533). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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. References

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

1. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine, "Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride," National Academy Press, Washington, DC, 1997.

2. Memorandum from Folmer, Division of Petition Review, Chemistry Review Group, to