

product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product DERAMAXX (deracoxib). DERAMAXX is indicated for the control of postoperative pain and inflammation associated with orthopedic surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DERAMAXX (U.S. Patent No. 5,521,207) from G. D. Searle L.L.C., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of DERAMAXX represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DERAMAXX is 1,675 days. Of this time, 1,578 days occurred during the testing phase of the regulatory review period, and 97 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) involving this animal drug product became effective:* January 21, 1998. The applicant claims January 27, 1998, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was January 21, 1998, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act:* May 17, 2002. FDA has verified the applicant's claim that the new animal drug application (NADA) for DERAMAXX (NADA 141-203) was initially submitted on May 17, 2002.

3. *The date the application was approved:* August 21, 2002. FDA has verified the applicant's claim that NADA 141-203 was approved on August 21, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 882 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by January 30, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 1, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management (see **ADDRESSES**). Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 29, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003F-0535]

Vulcan Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Vulcan Chemicals has filed a petition proposing that the food additive regulation for chlorine dioxide be amended to provide for an additional method for producing the additive.

DATES: Submit written or electronic comments on the petitioner's environmental assessment by December 31, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3014.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4A4751) has been filed by Vulcan Chemicals, P.O. Box 385015, Birmingham, AL 35238-5015. The petition proposes to amend the food additive regulations in § 173.300 Chlorine dioxide (21 CFR 173.300) to provide for an additional method for producing the additive.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and

comment. Interested persons may submit to the Division of Dockets Management written or electronic comments by December 31, 2003. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 13, 2003.

Laura M. Tarantino,

Deputy Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03-29744 Filed 11-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0391]

Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Precious Metal Alloys and Class II Special Controls Guidance Document: Dental Base Metal Alloys; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance documents entitled "Class II Special Controls Guidance Document: Dental Precious Metal Alloys" and "Class II Special Controls Guidance Document: Dental Base Metal Alloys." These guidance documents describe means by which gold-based alloys and precious metal alloys for clinical use and base metal alloy devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the

classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices presently classified in class II. In the proposed rule, FDA is also proposing to exempt these devices from premarket notification.

DATES: Submit written or electronic comments on these draft guidances by March 1, 2004, to ensure their adequate consideration in preparation of the final guidances. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance documents entitled "Class II Special Controls Guidance Document: Dental Precious Metal Alloys" and "Class II Special Controls Guidance Document: Dental Base Metal Alloys" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on these draft guidances to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, ext. 123, mea@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance documents entitled "Class II Special Controls Guidance Document: Dental Precious Metal Alloys" and "Class II Special Controls Guidance Document: Dental Base Metal Alloys." These guidance documents describe means by which gold-based alloys and precious metal alloys for clinical use and base metal alloy devices may comply with the requirement of class II special controls. Conformance with these guidance documents as special controls means that manufacturers will be able to introduce their device for commercial distribution in the United States without premarket notification and clearance. If these

guidance documents are made final, they will supersede "Guidance Document for the Preparation of Premarket Notifications [510(k)'s] for Dental Alloys" issued on March 3, 1997.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices presently classified in class II. If the proposed rule becomes final, manufacturers of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices will need to address the issues covered in these special controls guidances in order to be exempt from the 510(k) requirements of the Federal Food, Drug, and Cosmetic Act. However, the manufacturer need only show that its device meets the recommendations of the guidances or in some way provides equivalent assurances of safety and effectiveness. These draft guidance documents are not final nor are they in effect at this time.

II. Significance of Guidance

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances represent the agency's current thinking on gold-based alloys and precious metal alloys for clinical use and base metal alloy devices. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The collections of information addressed in the guidance documents have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910-0120). The labeling provisions addressed in the guidances have been approved by OMB under the PRA under OMB control number 0910-0485.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these draft guidances. Submit a single copy of electronic comments to <http://www.fda.gov/>