FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 30, 2001 (66 FR 17427), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0130. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25764 Filed 10–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0114]

Agency Information Collection Activities; Announcement of OMB Approval; Patent Term Restoration, Due Diligence Petitions, Filing, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions '' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 23, 2001 (66 FR 16249), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0233. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25837 Filed 10–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Use of Intraoral Appliance Models for Compliance With Biological Testing Requirements; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting information and comments on the use of intraoral appliance (IOA) models as a substitute for the animal caries reduction (''rat caries models'') biological test required by the monograph for over-the-counter (OTC) anticaries drug products to demonstrate the availability of fluoride in OTC dentifrice formulations. This notice is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written or electronic comments by January 14, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (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: Robert L. Sherman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The testing procedures for fluoride dentifrice drug products in 21 CFR 355.70 of the final monograph for OTC anticaries drug products (60 FR 52474, October 6, 1995), include both in vitro and biological testing to demonstrate the effectiveness of OTC anticaries dentifrices. The two in vitro tests (fluoride enamel uptake and enamel solubility reduction) demonstrate that fluoride is chemically available. The biological testing (animal caries reduction) assures that the fluoride is also bioavailable to alter tooth structure and make the tooth resistant to caries.

In the preamble to the final monograph for OTC anticaries drug products, FDA encouraged the development of additional testing procedures, such as remineralization tests. The agency noted that sufficient data were not available to correlate these tests specifically with clinical studies that demonstrate the effectiveness of fluoride dentifrices (60 FR 52474 at 52499). The agency stated that it would consider such tests as a substitute for the animal caries reduction test if adequate data were submitted demonstrating that an alternative testing procedure provides results of equivalent accuracy.

In 1996, FDA granted a petition (Refs. 1 and 2) that included the results of a study conducted in humans wearing an IOA with attached enamel chips as a substitute for the animal caries reduction test. Although the agency had initial concerns about the design and results of this IOA test, the data were considered sufficient to accept the test as an alternative to the animal caries model to demonstrate the effectiveness of the tested dentifrice formulation.

The petition also requested that the results of the IOA test be accepted as evidence of the effectiveness of the petitioner's other formulations. However, because these formulations contain different abrasives and flavorings, the agency determined that all other formulations must be tested individually (Ref. 2). The agency also recommended that protocols for any further IOA tests be submitted for review prior to conducting the tests.

IOA models employ small pieces of tooth enamel, mounted in the acrylic flanges of dentures worn by subjects that have been randomized to the various treatments to be investigated. The enamel chips are examined for demineralization or remineralization using various test methods. Proponents of the IOA model argue that, when compared with the animal caries reduction test, the IOA test is more