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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human 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 a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product INVANZ (ertapenem sodium). INVANZ is indicated for the treatment of adult patients with certain moderate to severe infections caused by susceptible strains of designated microorganisms. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INVANZ (U.S. Patent No. 5,478,820) from Syngenta Ltd., 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 human drug product had undergone a regulatory review period and that the approval of INVANZ 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 INVANZ is 2,273 days. Of this time, 1,916 days occurred during the testing phase of the regulatory review period, while 357 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: September 3, 1995. The applicant claims September 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 3, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: November 30, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for INVANZ (NDA 21–337) was initially submitted on November 30, 2000.

3. *The date the application was approve*d: November 21, 2001. FDA has verified the applicant's claim that NDA 21–337 was approved on November 21, 2001.

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 1,023 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 February 2, 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. 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.

[FR Doc. 03–29929 Filed 12–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1168]

Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Quantitative Risk Assessment and Risk Management Action Plan; Notice of Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that announced a public meeting to be held on December 4, 2003, in the **Federal Register** of November 7, 2003 (68 FR 63108). The location of the meeting at the FDA Center for Food Safety and Applied Nutrition Harvey W. Wiley Building in College Park, MD was incorrect. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lori Pisciotta, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2279, FAX: 301–436–2630, e-mail: *lpisciot@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 03–28005, appearing on page 63108 in the **Federal Register** of Friday, November 7, 2003, the following correction is made:

1. On page 63109, in the first column, under the *Location* paragraph, the correct address reads as follows: Harvey W. Wiley Building, 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

Dated: November 26, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30076 Filed 11–28–03; 11:23 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0306]

Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.'' This guidance document describes a means by which certain dental sonography and jaw tracking 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 final rule to classify certain types of these devices into class II (special controls).

DATES: Submit written or electronic comments on this guidance at any time. 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 guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices'' 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 concerning this guidance 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 14, 2002 (67 FR 52901), FDA published a proposed rule to classify certain dental sonography and jaw tracking devices into class II. In the **Federal Register** of August 14, 2002 (67 FR 53005), FDA also identified the document ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers'' as the special control, which in conjunction with general controls, is capable of providing reasonable assurance of safety and effectiveness for these devices. This guidance document describes a means by which certain dental sonography and jaw tracking devices may comply with the requirement of special controls for class II devices.

Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for the class II devices described in that final rule will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Interested persons were invited to comment on the draft guidance by November 12, 2002. FDA received no comments on the draft guidance document. FDA made minor revisions to the guidance to improve clarity and provide more detailed descriptions of our recommendations for electromagnetic compatibility testing and labeling.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on dental sonography and jaw tracking devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains 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 document 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 guidance 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 regarding this document. Submit a single copy of electronic comments to *http://wwww.fda.gov/dockets/ecomments* or two paper copies of any written comments, except that individuals may submit one paper 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.

V. Electronic Access

To receive ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1393) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturer's addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

Dated: October 23, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–29864 Filed 12–1–03; 8:45 am]

BILLING CODE 4160–01–S