application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written or electronic comments and petitions 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug 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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product AMEVIVE (alefacept). AMEVIVE is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AMEVIVE (U.S. Patent No. 5,547,853) from Biogen, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of AMEVIVE 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 AMEVIVE is 2,104 days. Of this time, 1,618 days occurred during the testing phase of the regulatory review period, while 486 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 (21 U.S.C. 355(i)) became effective (21 U.S.C. 355(i))*: April 29, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 29, 1997.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: October 2, 2001. FDA has verified the applicant's claim that the biological license application (BLA) for Amevive (BLA 12536) was initially submitted on October 2, 2001.

3. *The date the application was approved*: January 30, 2003. FDA has verified the applicant's claim that BLA 12536 was approved on January 30, 2003.

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 1,259 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 comments and ask for a redetermination by November 29, 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 March 29, 2005. 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: August 30, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–21874 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004M–0147, 2004M–0145, 2004M–0207, 2004M–0253, 2004M–0165, 2004M–0200, 2004M–0199, 2004M–0256, 2004M–0248, 2004M–0249, 2004M–0250, 2004M–0260, and 2004M–0259]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and

Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2004, through June 30, 2004. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2004 THROUGH JUNE 30, 2004.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P890064(S9)/2004M–0147	Digene Diagnostics, Inc.	DIGENE HYBRID CAPTURE 2 (HC2) HIGH–RISK HPV DNA TEST	March 31, 2003
P020006/2004M–0145	Enteric Medical Technologies, Inc.	ENTERYX PROCEDURE KIT	April 22, 2003
P970027/2004M–0207	Abbott Laboratories	ABBOTT AXSYM ANTIBODY TO HCV	February 5, 2004
P980007/2004M–0253	Abbott Laboratories	AXSYM FREE PSA	February 5, 2004
H020008/2004M–0165	Stryker Biotech	OP–1 PUTTY	April 7, 2004
P010014/2004M–0200	Biomet, Inc.	OXFORD MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	April 21, 2004
P030032/2004M–0199	Genzyme Biosurgery	HYLAFORM (HYLAN B GEL)	April 22, 2004
P030017/2004M–0256	Advanced Bionics Corp.	Precision Spinal Cord Stimulation (SCS) System	April 27, 2004
P030023/2004M–0248	Ophtec USA, Inc.	OCULAID/STABLEYES CAPULAR TENSION RINGS	April 27, 2004
P000054/2004M–0249	Wyeth Pharmaceuticals, Inc.	INFUSE BONE GRAFT	April 30, 2004
P030035/2004M–0250	St. Jude Medical	ST. JUDE FRONTIER BIVENTRICULAR CARDIAC PACING SYSTEM	May 13, 2004
P010062/2004M–0260	Euclid Systems Corp.	EUCLID SYSTEMS ORTHOKERATOLOGY (OPRIFOCOM A) CONTACT LENS FOR OVERNIGHT WEAR	June 7, 2004
P030045/2004M–0259	Ev3 Inc.	INTRASTENT DOUBLESTRUT STENT	June 8, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: September 23, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–21873 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0438]

Guidance for Industry: Use of Material from Bovine Spongiform Encephalopathy-Positive Cattle in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#174) entitled ''Use of Material from BSE-Positive Cattle in Animal Feed.'' This guidance document describes FDA's current thinking regarding the use in all animal feed of all material from cattle that test positive for BSE (bovine spongiform encephalopathy).

DATES: Submit written or electronic comments on agency guidances at any time.

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 on the guidance via the Internet at *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6860, e-mail: *burt.pritchett@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

BSE belongs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). These include BSE or ''mad cow'' disease in cattle; scrapie in sheep and goats; and classical and variant Creutzfeldt-Jakob diseases (CJD and vCJD) in humans. There is no known treatment for these diseases, and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for BSE or other TSEs that can be used to test for the disease in live animals or humans.

Under FDA's BSE feed regulation (21 CFR 589.2000) any protein-containing portion of mammalian animals is prohibited for use in feed for ruminant animals with the exception of certain products. FDA took this action to minimize the potential for any undetected BSE infectivity in animal feed to spread to ruminants via their feed. This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from cattle that test positive for BSE.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation in § 10.115(21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because FDA believes that, in light of the increased BSE testing activities by the U.S. Department of Agriculture, it is of public health importance to clarify that cattle that test positive for BSE are adulterated and are not to be used in any animal feed.

This guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a document in the **Federal Register**.

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 or two paper copies of any mailed 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

Copies of this guidance document may be obtained from the Center for Veterinary Medicine home page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: September 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22014 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0385]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus.'' This draft guidance document describes a means by which in vitro diagnostic devices for the laboratory diagnosis of Hepatitis A Virus 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 reclassify these device types from class III into class II (special controls).