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 office above 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: July 31, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–22265 Filed 8–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0272]

Determination of Regulatory Review Period for Purposes of Patent Extension; INTEGRA® Artificial Skin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INTEGRA® Artificial Skin and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device INTEGRA® Artificial Skin. INTEGRA® Artificial Skin is indicated for the post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INTEGRA® Artificial Skin (U.S. Patent No. 4,947,840) from the Massachusetts Institute of Technology, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 12, 1997, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of INTEGRA® Artificial Skin represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office represented that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INTEGRA® Artificial Skin is 4,477 days. Of this time, 3,173 days occurred during the testing phase of the regulatory review period, while 1,304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 30, 1983. FDA has verified the applicant's claim that the date the investigational device exemption (IDE), required under section 520(g)of the Federal Food, Drug, and Cosmetic Act, for human tests to begin became effective on November 30, 1983.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: August 6, 1992. The applicant claims May 4, 1990, as the date the premarket approval application (PMA) for INTEGRA® Artificial Skin (PMA P900033) was initially submitted. However, FDA records indicate that the PMA P900033, which was mailed May 4, 1990, was received by FDA on May 7, 1990. However, FDA notified the applicant that the PMA contained insufficient information for filing on June 22, 1990. After a number of additional documents were submitted to the PMA, the PMA was ultimately filed based on a document received August 6, 1992, which is considered the initially submitted date for the PMA.

3. *The date the application was approved*: March 1, 1996. FDA has verified the applicant's claim that PMA P900033 was approved on March 1, 1996.

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 923 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 20, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 17, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–22266 Filed 8–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grass Roots Biotechnology Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Grass Roots Biotechnology Meeting. The topics to be discussed are product classification (Biologic/Device/Drug/Food), the preapproval inspection process, the inspectional environment after product approval, and overall communications with the field offices. This meeting, which is cosponsored by FDA's Office of External Affairs and the New England District, Northeast Region; the Massachusetts Biotechnology Council; and the Biotechnology Association of Maine, is being held to promote the President's initiative for a partnership approach between frontline regulators and the people affected by the work of the agency.

Date and Time: The meeting will be held on Tuesday, September 23, 1997 (8 a.m. to 8:30 a.m. registration), 8:30 a.m. to 4 p.m.

Location: The meeting will be held at Ramada Hotel, 15 Middlesex Canal Park, Woburn, MA, 617–279–1675.

Contact: Donald J. Johnson, Special Assistant to the District Director, New England District Office, Northeast Region, Food and Drug Administration (HFR–NE 252), Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, 617–279–1675, ext. 129, FAX 617–279–1733.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Janice T. Bourque, Executive Director, Massachusetts Biotechnology Council, 245 First St., 14th Fl., Cambridge, MA 02142, 617–577–8198. Because attendance is limited to 100, preregistration is recommended. However, there is no cutoff date for registration.

If you need special accommodations due to a disability, please contact Donald J. Johnson at least 7 days in advance.

Supplementary Information: This meeting will feature a general session at which Federal regulations and procedures will be discussed, followed by four morning breakout sessions to identify problems or concerns in the topical areas, and four afternoon breakout sessions to recommend solutions to the problems or concerns identified previously.

A summary of the meeting will be provided to all registered participants. However, the public may request a summary of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857.

Dated: August 15, 1997.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 97–22267 Filed 8–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–94]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicaid Sterilization Regulations 45 CFR 96.73, 42 CFR 441 subpart F and Consent Form; *Form No.:* HCFA–R–94; *Use:* All Medicaid-eligible individuals seeking sterilization are required to sign the federally mandated consent form, acknowledging that they understand the benefits and risks of sterilization, and have received oral information concerning the sterilization operation from the provider. *Frequency:* Other (each time sterilization is sought); *Affected Public:* Individuals or Households; *Number of Respondents:* 112,526; *Total Annual Responses:* 112,526; *Total Annual Hours:* 140,658.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 11, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–22124 Filed 8–20–97; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–216]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and