ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)(19)	3,015	1	3,015	2	6,300
606.160(b)(1)(vii)	150	160	24,000	12.8	1,920
606.160(b)(1)(viii)	3,015	60	180,900	4.8	14,472
Total	.....	.....	.....	.....	22,422

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: December 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32882 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0400]

Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications.'' The PTC document is intended to provide manufacturers with preliminary guidance regarding the manufacture and preclinical evaluation of plasmid deoxyribonucleic acid (DNA) vaccines intended for clinical studies in preventive infectious disease indications and to assist manufacturers in the preparation of investigational new drug (IND) applications for use of these vaccines. This document is also intended to assist manufacturers with their product development plans for preventive vaccines for infectious diseases.

DATES: Written comments may be submitted at any time; however, to ensure comments are considered in any future revisions they should be submitted by February 25, 1997.

ADDRESSES: Submit written requests for single copies of ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the INTERNET may obtain the document using the World Wide Web (WWW) or bounce-back e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''plasmid@a1.cber.fda.gov''. Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this notice. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications.'' Plasmid DNA vaccines are defined as purified preparations of plasmid DNA designed to contain a gene or genes for the intended vaccine antigen as well as genes incorporated into the construct to allow for production in a suitable host system. The use of purified preparations of plasmid DNA constitutes a new approach to vaccine development.

The following topics are addressed in the PTC document to assist manufacturers with their product development plans: (1) CBER's approach to regulation of plasmid DNA preventive vaccines; (2) product considerations for an IND submission; (3) considerations for plasmid DNA vaccine modifications; (4) preclinical immunogenicity and safety evaluation; (5) use of adjuvants and devices to deliver the vaccine; (6) pre-IND meetings; and (7) IND submissions.

This PTC document is intended to provide manufacturers with information regarding concerns that are associated with the new technology of plasmid DNA preventive vaccines and to provide early guidance to the regulated industry. The goal is to create a regulatory environment that will encourage innovation and at the same time ensure that products are both safe and effective.

As with other PTC documents, FDA does not intend this PTC document to be all-inclusive and cautions that not all information may be applicable to all situations. The PTC document is intended to provide information and does not set forth requirements. FDA anticipates that manufacturers and other interested parties may develop alternative methods and procedures, and discuss them with FDA. FDA recognizes that advances will continue in the area of plasmid DNA vaccines and intends to update and revise the document in order to improve its usefulness.

Although the PTC document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent CBER's current thinking regarding issues related to plasmid DNA vaccines.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the PTC document. Two copies of any 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. A copy of the PTC document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether

further revision of the PTC document is warranted.

Dated: December 16, 1996.

William K. Hubbard.

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32930 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0490]

Advanced Bionics™ Corp.; Premarket Approval of the CLARION® Multi-Strategy Cochlear Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by the Advanced Bionics™ Corp., Sylmar, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CLARION® Multi-Strategy Cochlear Implant. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 22, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 27, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jane G. Fredericksen, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION: On June 30, 1994, the Advanced Bionics™ Corp., 12740 San Fernando Rd., Sylmar, CA 91342, submitted to CDRH an application for premarket approval of the CLARION® Multi-Strategy Cochlear Implant. The CLARION® Multi-Strategy Cochlear Implant is intended to restore a level of auditory sensation to individuals with profound sensorineural deafness via electrical stimulation of the auditory nerve. CLARION® is indicated for use in postlingually deafened adults, 18 years of age or older, with profound, bilateral, sensorineural deafness (greater than or equal to 90 decibels), who are unable to benefit from appropriately fitted hearing aids. Lack of aided benefit from a hearing aid is defined as scoring 20 percent or less on tests of open-set sentence recognition (i.e., Central Institute of the Deaf (CID) Sentences). Additionally, there should be no radiographic contraindications to receiver placement or electrode insertion.

On July 21, 1995, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended conditional approval of the application. On March 22, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 27, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–32880 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–605]

Agency information collection activities: Submission for OMB review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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: Revision of a currently approved collection; *Title of Information Collection:* Hospital Provider of Extended Care Services (Swing-Beds) in the Medicare and Medicaid Programs, 42 CFR 447.280 and 482.66; *Form No.:* HCFA–605; *Use:* This is a facility identification and screening form. It will be completed by a hospital that is requesting approval. It initiates the process of determining the hospital's eligibility and also requests approval for their bed count category. *Frequency:* Other (one time usage for initial application); *Affected Public:* Business