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

or other for profit, Not for profit institutions, and Federal Government; *Number of Respondents:* 1,500; *Total Annual Hours:* 375.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, 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 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 18, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–33020 Filed 12–26–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Library of Medicine (NLM); Opportunity for a Cooperative Research and Development Agreement for Research and Development of Document Imaging and Information Retrieval Software and Systems

AGENCY: Lister Hill National Center for Biomedical Communications, NLM, NIH, DHHS.

ACTION: Notice.

SUMMARY: The Lister Hill National Center for Biomedical Communications (LHNCBC), an R&D division of the National Library of Medicine, seeks a Cooperative Research and Development Agreement (CRADA) with a software company with a reputation in the software research, development and marketing communities, as demonstrated by the quality of its information products, particularly its document imaging and information retrieval software and systems.

The Collaborator must be able to collaborate with NLM staff to produce high quality information products. The Collaborator must have a demonstrated record of success in privately producing and marketing scientific information resources.

The term of the CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing no later than February 25, 1997. Parties should document their qualifications as identified in selection criteria in this initial submission. Parties will be subsequently selected for developing a formal proposal.

ADDRESSES: Inquires and proposals regarding this opportunity should be addressed to William Joseph Cotreau, J.D. (Tel. #301–496–0477, FAX #301–402–2177), Office of Technology Development, National Cancer Institute, Executive Plaza South, Suite 450, 6120 Executive Blvd. MSC 7182, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by LHNCBC pursuant to the Federal Technology Transfer Act of 1986, as amended by the National Technology Transfer Act (Pub. L. 104–1993 (1996)) and by Executive Order 12591 of October 10, 1987. The Communications Engineering Branch of LHNCBC is presently developing document-imaging systems, called DocView and WILL. DocView is a client-software package, based in the Microsoft Windows environment, designed to handle document images received over the Internet via scanning systems such as Ariel and external client software such as MIME E–mail or Web browers. WILL is a document-sending system, integrating a scanner, PC, image processing boards, printer, barcode reader, fax, and other equipment. WILL is designed to automate almost all aspects of document production, from retrieval of requests to document delivery, and updating of request status.

Under the present proposal, the goal of the CRADA will be the development of the following technology:

- Development of Macintosh and Unix versions for DocView;
- Development of Netscape® Plug-in modules for Macintosh and Unix versions of DocView;
- Development of WILL for faster document capture, improved user interface, improved scanning abilities, and replacement of the present file management with a more efficient DBMS; and
- Development of an improved document-request interface for WILL.

All necessary existing rights and assets currently held by LHNCBC for the production of identified software will be transferred as needed to the Collaborator.

Party Contributions

The role of the LHNCBC includes the following:

(1) Provide Collaborator with the DocView and WILL source codes, if and as necessary, and all licenses necessary for the further development of DocView and WILL;

(2) Provide staff, expertise, and materials for the development of DocView software and the WILL system;

(3) Evaluate the work product of Collaborator to ensure progress toward meeting the CRADA goals; and

(4) Provide work space and equipment for production and testing of any document-retrieval software products developed.

The role of the successful Collaborator will include the following:

(1) Provide funding, if and as necessary, in support of production and dissemination of DocView and WILL;

(2) Provide expertise and assistance in the production and marketing of DocView and WILL;

(3) Provide staff, expertise, and materials for the development of DocView and WILL software; and

(4) Provide quality assurance testing, operator training, and user support for any document-manipulation software products resulting from this CRADA.

Selection Criteria

Proposals submitted for consideration should fully address each of the following qualifications:

(1) Expertise:

A. Demonstrated expertise in developing and producing high quality document imaging software and systems;

B. Demonstrated ability to secure national and international marketing and distribution of software;

C. Demonstrated expertise in overseeing all aspects of product development;

D. Demonstrated intellectual ability to guide development of product line which addresses the requirements of LHNCBC;

E. Demonstrated expertise in serving and supporting a significant client base; and

F. Familiarity with library systems and interlibrary loan and document delivery services.

(2) Reputation: The successful Collaborator must be reorganized in the software industry for:

A. Producing, marketing and supporting quality document imaging software;

B. Indications of high levels of satisfaction by software experts, libraries, document suppliers and