Committee, dated April 1984, and the Panel on Review of Allergenic Extracts, dated December 1983, that are the subject of this proposed order. Copies of these reports can be obtained from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. By sending a self-addressed adhesive label, you will assist that office in processing your requests more quickly. The documents 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, or by mail by contacting CBER electronically at www.CBER__INFO@CBER.FDA.GOV.

Interested persons may, on or before August 13, 2000 submit written comments regarding this proposal to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments should be submitted, except that individuals should submit one copy. Comments may also be submitted electronically at www.fda.gov/ohrms/dockets. Comments should be identified with the docket number found in brackets in the heading of this document. Data and information submitted to FDA that fall within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) are not available for public disclosure. Consistent with the provisions of § 601.25(b), when FDA publishes this proposed order and the Reclassification Committee's reclassification findings, data and information submitted to FDA in connection with these reclassified products will be made publicly available after June 14, 2000, and may be viewed at the Dockets Management Branch (address above). Data and information submitted and shown to fall within the confidentiality provisions of one or more of the above statutes will not be disclosed. Comments concerning confidentiality should be received by FDA by June 14, 2000. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After review of the public comments received in response to this proposed order and in consideration of the results of hearings, if any, FDA intends to issue in the **Federal Register** a final order announcing its final conclusions and revoking those licenses which are placed in Category II by the final order.

Dated: May 3, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–12116 Filed 5–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0228]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neuro Cybernetic Prosthesis (NCP®) System; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a previous determination regarding the regulatory review period for the Neuro Cybernetic Prosthesis (NCP®) System that appeared in the **Federal Register** of November 10, 1998 (63 FR 63066). FDA is amending the notice because the agency agrees with the information provided in a request from the applicant for revision of the regulatory review period (Request) (Docket No. 98E–022 8/PRC 1, dated and received on January 8, 1999).

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: In its original application for patent term extension, the applicant claimed December 16, 1991, as the date the premarket approval application (PMA) for the Neuro Cybernetic Prosthesis (NCP®) System (PMA 910070) was initially submitted. FDA first determined that the PMA was initially submitted on January 27, 1997, because FDA records indicated that the PMA submitted on December 16, 1991, had not been filed, but an amended PMA, renumbered as PMA 970003, was the PMA for the approved product.

The applicant later claimed in its request that FDA's determination of the regulatory review period failed to take into account an approved amendment to the applicant's originally submitted PMA. Therefore, the applicant requested that the agency correct the date the PMA was initially submitted to June 1, 1993, the date the approved amendment to the PMA was received by FDA.

FDA reviewed its records and confirmed that the amended PMA, received on June 1, 1993, was filed by the agency based on a threshold determination that the amended PMA was sufficiently complete to permit a substantive review. FDA later determined that additional studies were required and issued a major deficiency letter dated September 30, 1994, requesting that additional clinical studies be performed. The applicant submitted a second amendment to the PMA, which the agency received on January 27, 1997. FDA reviewed the amendment and determined that the second amendment sufficiently responded to the September 30, 1994, deficiency letter, and filed the newly amended PMA on the date of the receipt of the completed PMA, January 27, 1997. For administrative reasons, the second amendment to the PMA was considered a resubmission of the PMA, and it was assigned a new PMA number, P970003, which is the PMA number of the approved PMA for the product.

In the past, FDA has determined that the start of the approval phase began with the submission of the first filed PMA for an approved product, even if the original filed PMA was later withdrawn and filed under a new number. For this reason, FDA now accepts the date of June 1, 1993, submitted by the applicant in its request, as the date the first PMA was filed for the product and the date that the PMA was initially submitted.

Therefore, the applicable regulatory review period for the Neuro Cybernetic Prosthesis (NCP®) System is 3,237 days. Of this time, 1,730 days occurred during the testing phase of the regulatory review period, while 1,507 days occurred during the approval phase.

These periods of time were derived from the following dates, summarized from the November 10, 1998, notice and modified by this technical amendment:

1. *The date a clinical investigation involving this device was begun:* September 6, 1988.

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):* June 1, 1993.

3. *The date the application was approved:* July 16, 1997.

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 1,761 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 14, 2000, 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 November 13, 2000, for a determination on 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. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 6, 2000.

Jane A. Axelrad,

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

[FR Doc. 00–12117 Filed 5–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Children's Hospital Graduate Medical Education Program—New

Public Law Number 106–129 amended the Public Health Service Act to establish a new program to support graduate medical education (GME) in children's hospitals. The provision authorizes payments in FY 2000 and FY 2001 for direct and indirect expenses associated with operating approved GME programs. Section 340E(c)(1) states that the amount determined under this subsection for payments for direct medical expenses for a fiscal year is equal to the product of (A) the updated per resident amount as determined, and (B) the average number of FTE residents in the hospital's approved graduate medical residency training programs as determined under section 1886(h)(4) of the Social Security Act during the fiscal year. The statute directs the Secretary to take into account factors identified in section 340E(b)(1)(B) and 340E(d)(2) '' case mix, number of FTE residents, treatment of more severely ill patients and the additional costs related to teaching residents.

Administration of the Children's Hospital Graduate Medical Education Program relies on the reporting of the number of full-time equivalent residents in applicant children's hospital training programs to determine the amount of direct and indirect expense payments to participating children's hospitals. Indirect expense payments will also be derived from a formula that requires the reporting of case mix index information from participating children's hospitals.

Hospitals will be requested to submit such information in an annual application. The statute also requires reconciliation of the estimated numbers of residents with the actual number determined after the close of the fiscal year. Participating children's hospitals would be required to complete an adjusted report to correct such information on an annual basis.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondent	Total responses	Hrs. per response	Total hour burden
Form E (Short)	42	1	42	*99.9	4,194
Form E (Long)	12	1	12	*46.7	560
Form F (Short)	42	1	42	8	336
Form F (Long)	12	1	12	8	96
IME Data*	54	1	54	14	756
Required GPRA Tables	54	1	54	28	1,512
Total	54				7,454

*The hours per response are paradoxically greater for the short form because of the relatively large number of hospitals which have been reporting residency counts to Medicare but expect considerable work in translating resident counts based on hospital cost-reporting years to counts, in part prospective, based on Federal fiscal years, including obtaining interim counts from other hospitals of incoming rotations.

HRSA is requesting from OMB an emergency review and approval of this data collection within 40 days from the date of publication of this notice, with a 180-day approval period. During this 180-day approval period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day review and public comment period on the data collection activity.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, 725 17th St., NM, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 8, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–11893 Filed 5–12–00; 8:45 am]

BILLING CODE 4160–15–P