F. Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

*All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, and American Samoa have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-three jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodate or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, Head Start Bureau, 330 C Street S.W., Washington, D.C. 20447, Attn: Head-Start Quality Research Centers. A list of the Single Points of Contact for each State and Territory can be found on the web site http://www.whitehouse.gov/omb/grants/spoc.html

Dated: August 30, 2000.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 00–22772 Filed 9–5–00; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Reallotment of Funds for FY 1999 Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice of determination concerning funds available for reallotment.

SUMMARY: In accordance with section 2607(b)(1) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 8621 *et seq.*), as amended, a notice was published in the **Federal Register** on July 19, 2000 (65 FR 44791) announcing the Secretary's preliminary determination that $496,085 in FY 1999 Low Income Home Energy Assistance Program (LIHEAP) funds may be available for reallotment. The two grantees whose FY 1999 funds were subject to reallotment were notified of the Secretary's preliminary determination, and neither commented during the 30 days allowed for that purpose.

Pursuant to the statute cited above, funds will be realloted to all LIHEAP grantees based on the normal allocation formula as if they had been appropriated for FY 2000. No subgrantees or other entities may apply for these funds.

FOR FURTHER INFORMATION CONTACT: Janet Fox, Director, Division of Energy Assistance, Office of Community Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447; telephone number (202) 401–9351.

Dated: August 30, 2000.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 00–22751 Filed 9–5–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99D–4575 and 99D–4576]

Agency Information Collection Activities; Announcement of OMB Approval; Food Additives; Food-Contact Substances Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Additives; Food-Contact Substances Notification System'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 31, 2000 (65 FR 34713), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. This information collection considers only those submissions required by statute under section 409(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)(1)).

In a proposed rule published in the **Federal Register** of July 13, 2000 (65 FR 43269), FDA requested approval for the information collection required by statute under section 409(h)(1) of the act plus additional information collection that regulated industry has requested FDA to accept. The information collection burden discussed in the July 13, 2000, proposed rule will be considered by OMB in light of this approval, and comments received in response to the additional information collection in the proposed rule.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0444. The approval expires on August 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–22701 Filed 9–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0788]

Neurological Devices; Reclassification of the Totally Implanted Spinal Cord Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment the recommendation of the Neurological Devices Panel (the Panel) to reclassify the totally implanted spinal cord stimulator (SCS) for treatment of chronic intractable pain of the trunk or limbs from class III into class II. The Panel made this recommendation after reviewing the reclassification petition submitted by Advanced Neuromodulation Systems, Inc. (ANS), and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.''

DATES: Submit written comments by October 6, 2000.

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

FOR FURTHER INFORMATION CONTACT: Russell P. Pagano, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the 1976 amendments enactment date), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. A postamendment device remains in class III and requires premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section allows FDA to initiate reclassification of a postamendments class III device under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. To change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs is a postamendments device classified into class III under section 513(f)(2) of the act. Therefore, the device cannot be placed in commercial distribution for treatment of chronic intractable pain of the trunk or limbs unless it is reclassified under section 513(f)(2) of the act, or subject to an approved PMA under section 515 of the act.

This action is taken in accordance with section 513(f)(2) of the act and § 860.134 of the regulations, based on information in the ANS petition submitted on June 16, 1999. ANS requested reclassification of totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs from class III into class II. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested reclassification.

III. Device Description

The following device description is based on the Panel's recommendations and the agency's review: The totally implanted SCS consists of an implanted