Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The ''Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals'' will provide information on the frequency, nature, and scope of reuse and reprocessing of single-use medical devices by U.S. hospitals. The survey will provide statistically reliable estimates of the number of U.S. hospitals that are currently reusing and internally reprocessing single-use medical devices, whether they have registered with FDA, whether they are aware of the FDA educational materials on the reuse of single-use medical devices, and, if they are not currently internally reprocessing single-use devices, whether they have reused and reprocessed single-use medical devices in the past 3 years.

FDA will use these results to estimate the number of U.S. hospitals that reused and reprocessed single-use medical devices in the past, and those that currently reuse and internally reprocess single-use medical devices. This information will help FDA design its inspection plan, modify its education program, and evaluate the economic impact of current and future policies regarding single-use medical devices. The respondents to this collection of information will be U.S. hospitals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR TELEPHONE SURVEY[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4,480	1	4,480	0.125	560

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a one-time survey. The burden estimate for the telephone survey is based on a pretest of a preliminary survey instrument administered to nine hospitals.

Dated: April 24, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–10626 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0170]

Abbott Laboratories' Sarafloxacin for Poultry; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) sponsored by Abbott Laboratories. The NADAs provide for use of sarafloxacin to treat poultry. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations by removing the portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, North Chicago, IL 60064, is sponsor of the following NADAs: (1) NADA 141–017 SaraFlox® (sarafloxacin hydrochloride) WSP, a water-soluble powder used in the drinking water of broiler chickens and growing turkeys for control of mortality associated with *Escherichia coli* in (21 CFR 520.2095); and (2) NADA 141–018 SaraFlox® (sarafloxacin hydrochloride) Injection, an injectable solution used in 18-day embryonated broiler eggs and day-old broiler chickens for control of early chick mortality associated with *E. coli* (21 CFR 522.2095).

The sponsor was informed by FDA that, on the basis of new data and information before it, there is a question of human food safety, due to the use of fluoroquinolones such as sarafloxacin in poultry. After being informed by FDA of this question, Abbott Laboratories requested voluntary withdrawal of approval of NADAs 141–017 and 141–018. By doing so, the firm waived its opportunity for hearing.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84),

and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 141–017 and 141–018, and all supplements and amendments thereto is hereby withdrawn effective April 30, 2001. Any new animal drug product that is not the subject of an approved application is subject to regulatory action at any time.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: April 17, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–10067 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0788]

Neurological Devices; Reclassification of the Totally Implanted Spinal Cord Stimulator; Denial of Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has denied a petition submitted by Advanced Neuromodulation Systems, Inc. (ANS), 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. FDA had previously made available for public comment the recommendation of the Neurological Devices Panel (the Panel) on the reclassification petition and FDA's tentative findings on the Panel's recommendation. After considering all the available information, including the public comments on the Panel's recommendation, FDA denied the reclassification petition by order in a letter to the petitioner.

ADDRESSES: A copy of the denial order is available at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

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 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.

Reclassification of classified postamendments devices is governed by section 513(f)(3) 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 a manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order reclassifying the device in class I or class II.

FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such postamendment 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)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a reclassification petition to a device panel for a recommendation on the subject device's classification. 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.

On June 16, 1999, ANS submitted a petition to FDA that requested reclassification of the 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 spinal control stimulator consists of an implanted pulse generator (IPG), leads, and electrodes. The IPG contains the internal power source that is implanted in the patient. The electrodes are placed on the patient's spinal cord and the leads from the electrodes are connected subcutaneously to the IPG.