conditions: (1) It is intended for use by a patient or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device, and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA Form 3514 was developed to assist respondents in organizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.81 and 807.87 (part 807, subpart E)		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Total						321,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,000	10	20,000	0.5	10,000
Total					10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document. The total burden for using voluntary FDA Form 3514 is estimated to be approximately 1,000 hours and has been included in this information collection. Once this information collection has been approved, the burden for FDA Form 3514 will be reported and approved in each of the following OMB information collections: 0910–0078, Investigational Device Exemption Reports and Records; 0910–0231, Premarket Approval of Medical Devices; and 0910–0332, Medical Devices, Humanitarian Devices.

Dated: April 24, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–10624 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–0175]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed voluntary survey of hospitals to collect information on the extent and nature of current practice of reprocessing of single-use medical devices by these institutions.

DATES: Submit written or electronic comments on the collection of information by June 29, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edocketthome.cfm. Submit written comments on the collection of information to the Dockets Management

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),