TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
170.36	25	1	25	150	3,750
570.36	5	1	5	150	750
Total					4,500

[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 Record	Total Hours
170.36(c)(v)	25	1	25	15	375
570.36(c)(v)	5	1	5	15	75
Total					450

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

In the proposed rule, FDA estimated that the Center for Food Safety and Applied Nutrition (CFSAN) would receive approximately 50 GRAS notices per year and that the Center for Veterinary Medicine (CVM) would receive approximately 10 GRAS notices per year. Although FDA requested comment on this estimate, the comments did not provide useful information regarding this issue. Therefore, FDA evaluated the number of notices received by CFSAN to date. CFSAN received 274 GRAS notices during the 11-year period from 1998 through 2008, for an average of approximately 25 GRAS notices per year. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices submitted to CFSAN to be 25 or less. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM to be 5 or less.

Dated: February 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2861 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0571]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Compliance With the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly ''Reprocessed Single-Use Device Labeling'')

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 13, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submissions@OMB.eop.gov*. All comments should be identified with the OMB control number 0910–0577. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry and Food and Drug Administration Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly ''Reprocessed Single-Use Device Labeling'') (Federal Food, Drug and Cosmetic Act, Section 502(u)) (OMB Control Number 0910–0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 502 of the act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Thus, the name for this information collection activity has been changed to

more accurately describe the information collection content.

Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse, may identify itself using a detachable label that is intended to be affixed to the patient record.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 10 establishments that distribute approximately 1,000 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 100 hours.

In the **Federal Register** of November 17, 2008 (73 FR 67873), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received one comment in support of the collection of information stating that it is necessary to help reprocessors of SUDs comply with section 502(u) of the act. The comment further stated that the estimated reporting burden did not appear excessive.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
502(u)	10	100	1,000	.1	100

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

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2902 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0026]

Apothecon et al.; Withdrawal of Approval of 103 New Drug Applications and 35 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 103 new drug applications (NDAs) and 35 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective March 13, 2009.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 7–335	Pronestyl (procainamide hydrochloride (HCl)) Capsules and Injection	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 7–935	Phenergan (promethazine HCl) Tablets	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 9–193	Cogentin (benztropine mesylate) Tablets	Merck & Co., Inc., Sunneytown Pike, P.O. Box 4, BLA–20, West Point, PA 19486
NDA 9–986	Deltasone (prednisone) Tablets	Pharmacia & Upjohn Co., c/o Pfizer, Inc., 235 East 42d St., New York, NY 10017
NDA 10–374	Medihaler-Epi (epinephrine bitartrate)	3M Pharmaceuticals, 3M Center, Bldg. 0275–05–W–12, St. Paul, MN 55144–1000
NDA 10–375	Medihaler-ISO (isoproterenol)	Do.
NDA 10–598	Bendectin (doxylamine succinate and pyridoxine HCl) Tablets	Sanofi-Aventis, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807–0977