the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded.

Based on information taken from our databases, FDA estimates that there are 29,370 owner/operators who collectively register a total of 33,490 device establishments. The number of respondents listed for section 224 of FDAAA in Table 1 of this document is 29,370, which corresponds to the number of owner/operators who annually register one or more establishments. In addition, FDA estimates that 4,988 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in Table 1 of this document for section 223 of FDAAA is 24,382, which corresponds to the number of owner/operators who annually list one or more devices (29,370 - 4,988 = 24,382).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than one-tenth of 1 percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than 1 percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 21 waiver requests, which could increase by only one additional request each year.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in Table 2 of this document, complies with the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only upon request from FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

Dated: September 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22989 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0512]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices: Humanitarian Use Devices

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Humanitarian Use Devices.

DATES: Submit written or electronic comments on the collection of information by December 1, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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, including each proposed extension of an existing 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 these topics: (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.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814 (OMB Control Number 0910–0332)—Extension

This collection of information implements the humanitarian use device (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the act, FDA is authorized to exempt a HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted, because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease

or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt a HUD from the effectiveness requirements under sections 514 and 515 of the act, provided that the device meets requirements set forth under section 520(m) of the act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of a HUD is in compliance with the HUD provisions under section 520(m) of the act.

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

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
814.102	14	1	14	40	560
814.104	6	1	6	320	1,920
814.106	6	2	12	50	600
814.108	32	1	32	80	2,560
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.24(b)	4	1	4	2	8
814.126(b)(1)	45	1	45	120	5,400
Total					11,054

[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
814.126(b)(2)	45	1	45	2	90
Total					90

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

The number of respondents in Tables 1 and 2 of this document are an average from data for the previous 3 years, i.e., FY 2005–2007. The number of annual reports submitted under § 814.126(b)(1) in Table 1 reflects an increase to 45 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in Table 2, the number of recordkeepers increased to 45.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: September 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22991 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0506]

Determination That ATROVENT (Ipatropium Bromide) Inhalation Solution and 10 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 11 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term