SUPPORTING STATEMENT
REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF
DRUGS IN COMMERCIAL DISTRIBUTION

A. Justification

1. Circumstances of Information Collection

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement Section 510 of the act, FDA issued part 207 (21 CFR part 207). Under current[1] 21 CFR 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and

1 This notice requests comments on the information collection in current part 207. In the Federal Register of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the information collection for revised part 207 will replace the information collection in this notice.

product listing requirements if they import or offer for import their products into the United States.

Under current §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA-2656 (Registration of Drug Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA-2656e (Annual Update of Drug Establishment) (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in the table below by the information submitted annually on Form FDA-2656). Changes in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as amendments to registration under current § 207.26 within 5 days of such changes. Distributors that elect to submit drug listing information must submit a Form FDA-2656 to FDA and a copy of the completed form to the registered establishment that manufactured the product to obtain a labeler code. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time by using Form FDA-2657 (Drug Product Listing). Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information by using Form FDA-2658 (Registered Establishments' Report of Private Label Distributors).

Under current § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug

application number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product not subject to an approved application or license, the National Drug Code number, and any drug imprinting information.

In addition to the product listing information required on Form FDA-2657, FDA may also require, under current § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under current § 207.30, establishments must update their product listing information by using Form FDA-2657 and/or Form FDA-2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list; (2) all drug or biological products formerly listed for which commercial distribution has been discontinued; (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed; and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

2. Purpose and Use of Information

The information obtained from the establishment registration form FDA 2656 is used by FDA and other government agencies to keep an accurate and current list of all human and animal drug manufacturers, repackers, relabelers and other drug processors located in this country. This list is used by FDA for inspectional purposes as required by the Act. In addition, the data is used by the public and private sector as a listing of the names and locations of drug firms.

The information obtained from the listing forms FDA-2657 and FDA-2658 is used, through assignment of the National Drug Code numbers, for third party reimbursement payment in Medicare and Medicaid as well as other health care insurance firms. Use of the assigned NDC numbers on insurance reimbursement forms is essential for payment. The NDC numbers also help industry, retailers, wholesalers and so on, as well as large government purchasing agencies such as the Defense Department, to maintain an accurate list of drug products for inventory purposes. The data obtained from the listing forms is also used by FDA to determine which products containing certain drug ingredients may be found to be unsafe or not effective. In addition, the data is used to produce a National Drug Code Directory to meet demands of the drug and health care industry for a complete list of prescription drugs marketed in the United States. The listing information is also used for the assessment of certain user fees.

If the collection of this information were not conducted, there would be no third-party reimbursement for drugs. Also, many systems which rely on drug inventories would be hindered as well as FDA's efforts to regulate the drug industry. Concerning the drug imprint information, poison control centers use imprinted drug codes to help identify drug products in overdose emergencies. Consumers and health professionals use imprinted drug codes to recognize

whether a different manufacturer's product has been dispensed or whether a prescription has been incorrectly filled. Imprinting can also aid in the prevention of emergencies caused by tampering. It can also assist law enforcement, regulatory, and other public officials to trace counterfeit and defective drug products.

3. Use of Improved Information Technology

In the Federal Register of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the information collection for revised part 207 will replace the information collection in this notice.

4. Efforts to Identify Duplication

Although several systems do exist in FDA that have related data, they exist for different uses. This information is not already submitted to the agency, and thus, there is no duplicate reporting.

5. Involvement of Small Entities

Data collection for purposes of this regulation may include small businesses. FDA has established a Division of Small Manufacturers Assistance to provide workshops, onsite evaluations, and other technical assistance to small manufacturers. Each FDA Field Office has small business representatives which help small businesses fill out forms, discuss regulatory requirements, and provide clarification to firm registration and drug listing matters.

6. Consequences If Information Collected Less Frequently

Information on the registration of drug firms and the listing of drug products cannot be collected less frequently. FDA believes that in order to fulfill its statutorily mandated responsibility under Section 510 of the Act, the agency needs to keep its listing current with changes in the industry.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

None of the collection requirements are inconsistent with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

In the Federal Register of August 24, 2007 (72 FR 48656), FDA published a notice requesting comment on this information collection. No comments were received on the information collection estimates. As discussed under section 3 above, in the Federal Register of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. FDA is now preparing a final rule which responds to the public comments received on the proposal.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this provision.

10. Assurance of Confidentiality

Confidentiality of drug listing information is safeguarded by 21 CFR 207.37.

11. Questions of a Sensitive Nature

This information collection does not contain questions pertaining to sex, behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Hour Burden

The information collection requirements of the Drug Listing and Establishment Registration regulations have been grouped according to the information collection areas of the regulations. The estimates are based upon registration and listing data collected and compiled in FDA's Office of Compliance

FDA estimates the annual information collection burden for current part 207 as follows:

Form	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours Per Responses	Total Hours
(1) Form FDA-2656 – *Registration of Drug Establishment* (New registrations, including new labeler codes for private label distributors)	39	14.72	574	2.50	1,435
(2) Form FDA-2656 – *Annual Update of Drug Establishment* (Update of registration information)	3,256	2.99	9735	2.50	24,338
(3) Form FDA-2657 – *Drug Product Listing* (New drug listings)	1,567	6.57	10,295	2.50	25738
(4) Form FDA-2658 – *Registered Establishments' Report of Private Label Distributors* (New listings for private label distributor drugs)	146	10.06	1,469	2.50	3673
(5) Form FDA-2657 and Form FDA-2658 – (June and December updates of all listing information)	1,677	11.21	18,799	2.50	46,992.
Total					102,176

13. Estimates of Annualized Cost Burden to Respondents

Based on an industry hourly wage average cost of $50 per hour, the annual cost is as follows:

Total burden hours of 102,260 @ $50 per hour equals $5,113,000.

14. Estimates of Annualized Cost Burden to the Government

FDA currently devotes approximately 30 FTEs to maintaining the registration and listing database for human and veterinary drugs and biologics. If each FTE equals approximately $250,000, the total cost to the government is approximately $7,500,000.

15. Changes in Burden

The decrease in burden hours results from revised, more accurate, registration and listing data information, and steps taken to convert from a paper to an electronic information collection system.

16. Time Schedule, Publication, and Analysis Plans

No comprehensive tabulation of the data is planned or anticipated.

17. Displaying of OMB Expiration Date

The FDA Forms involved in this collection will display the OMB expiration date.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19, A Certification for Paperwork Reduction Act Submission, of OMB Form 83-I.