

as an extension of the prior approval of collection of this data via a different media, i.e., paper. There are additional data elements that filers can provide to FDA along with other entry-related information that, by doing so, may result in their receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin FDA-regulated products are offered for import, FDA is notified through CBP's Automated Commercial System (ACS) by the importer (or his agent) of the arrival of each entry. Following such notification FDA reviews relevant data to ensure the imported product meets the standards as are required for domestic products, makes an admissibility decision, and informs the importer and CBP of its decision. A single entry frequently contains multiple lines of different

products. FDA may authorize specific lines to enter the U.S. unimpeded, while others in the same entry are to be held pending further FDA review/action.

An important feature developed and programmed into FDA's automated system is that all entry data passes through a screening criteria program. FDA's electronic screening criteria module makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Virtually instantaneously after the entry is filed, the filer receives FDA's admissibility decision covering each entry, i.e., "MAY PROCEED" or "FDA REVIEW."

Examples of FDA's need to further review an entry include: Products originating from a specific country or manufacturer known to have a history of problems, FDA has no previous knowledge of the foreign manufacturer and/or product, and an import alert covering the product has been issued, etc. The system assists FDA entry reviewers by notifying them of

information such as the issuance of import alerts, thus averting the chance that such information will be missed.

With the inception of the interface with CBP's ACS, FDA's electronic screening criteria program is applied nationwide. This virtually eliminates problems such as "port shopping," e.g., attempts to intentionally slip products through one FDA port when refused by another, or to file entries at a port known to receive a high volume of entries. Every electronically submitted entry line of foreign-origin FDA-regulated product undergoes automated screening described previously in this document. The screening criteria can be set to be as specific or as broad as applicable; changes are virtually immediately effective. This capability is of tremendous value in protecting the public in the event there is a need to immediately halt a specific product from entering the United States.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,727	1,070	3,988,371	.263	1,048,447

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

Dated: February 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration certain authorities vested in the Secretary, Health and Human Services (HRSA) under Section 307(C), Title III of the Denali Commission Act of 1998, as amended hereafter, pertaining to the Denali Commission's Demonstration Health Projects.

This delegation shall be exercised in accordance with the Department's applicable policies, procedures and guidelines relating to regulations.

In addition, I have affirmed and ratified any actions taken by the HRSA Administrator, or other HRSA officials, which involved the exercise of these

authorities prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: February 9, 2009.

Charles E. Johnson,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration, certain authorities vested in the Secretary of Health and Human Services under Section 219 of Public Law 110-161, as amended hereafter, pertaining to the Delta Health Initiative.

These authorities may be redelegated.

This delegation excludes the authority to issue regulations and to submit reports to Congress, and shall be exercised in accordance with the

Department's applicable policies, procedures, and guidelines.

In addition, I have affirmed and ratified any actions taken by the Administrator, or other HRSA officials, which involved the exercise of these authorities prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: February 9, 2009.

Charles E. Johnson,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Professions Preparatory, Indian Health Professions Pregraduate and Indian Health Professions Scholarship Programs

Announcement Type: Initial.

CFDA Numbers: 93.971, 93.123, and 93.972.

Key Dates:

Application Deadline: February 28, 2009, for Continuing students.