

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

TITLE OF INFORMATION COLLECTION:

Online Survey of Commercial Pharmaceutical Product Importers

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. What is the problem to be investigated:

The globalization of the pharmaceutical market has created serious challenges for FDA, including dramatic increases in drug product imports, complex and fragmented global supply chains, and increasing threats of fraudulent and substandard drugs. Congress has recently passed several legislative authorities, including Title VII of FDASIA (Pub. L. 112–144) and the Drug Supply Chain Security Act (DSCSA), to amend the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide FDA with important authorities to respond to these challenges and better ensure the safety, effectiveness, and quality of drug products. In order to develop an efficient regulatory strategy, FDA urgently needs to understand what types of entities are currently importing drugs into the United States and what practices they are engaged in. FDA also needs to learn how commercial importers may respond to a possible requirement to register with FDA and provide detailed lists of their imported drug products, their constituents, and associated importing practices. This online survey will provide FDA with crucial information about importer characteristics, importer practices, and how best to use its new authorities to streamline the flow of drug shipment data to FDA, thereby helping FDA to ensure the safety of imported commercial drug products and protect American consumers from distribution of non-compliant drug products.

2. Please describe the method to obtain the convenience sample:

FDA maintains data on imports of all FDA-regulated products into the U.S. In addition to the type of product being imported and FDA's admissibility decision for the import line, the database contains a field indicating the importer of the product. Using the latest 12 months of import data, FDA has matched this database to that of Dun & Bradstreet using the name and address of the importer yielding additional information fields, such as industry NAICS code. FDA plans to select a sample of importers of human and animal drug products from this database.

3. Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2011 Justification Statement:

YES / NO (if no skip to #5)

NO.

If yes, please describe:

Not applicable.

4. Burden Chart and Description:

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Importers of commercial pharmaceutical drug products: Response	475	35 minutes	277 hours
Importers of commercial pharmaceutical drug products: Non-response	1,425	2 minutes	48 hours
Importers of commercial pharmaceutical drug products: Total	1,900	NA	325 hours

5. Attach Questions

See attachment.

REQUESTED APPROVAL DATE: 04/14/2017

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FDA CENTER: Office of the Commissioner & CDER