Guidance for Industry (GFI) and FDA Staff: Dear Health Care Provider Letters (DHCP); Improving Communication of Important Safety Information

OMB Control No. 0910-0754

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 375(b)) (the FD&C Act), the Secretary may cause dissemination of information regarding drugs in situations involving, in the opinion of the Secretary, "imminent danger to health, or gross deception of the consumer." Food and Drug Administration (FDA) regulations at § 200.5 (21 CFR 200.5) outline the general provisions for the "[m]ailing of important information about drugs," but do not provide instructions on the format and content of the actual letter. To assist manufacturers and distributors in this regard, FDA has developed a guidance entitled, "*GFI: Dear Health Care Provider Letters: Improving Communication of Important Safety Information*." The guidance provides recommendations on (1) when to issue a DHCP letter, (2) the types of information to include in a DHCP letter, (3) how to organize that information so that it is communicated effectively to health care providers, and (4) formatting techniques to make the information more accessible. FDA is therefore requesting approval of the information collection provisions associated with the guidance.

2. Purpose and Use of the Information Collection

The information collection provides a means for manufacturers, distributors, (individuals) and the FDA (Federal Government) to communicate directly with health care providers responsible for patient care about new or updated information regarding a human drug or biologic. A DHCP letter is one of the mechanisms used to communicate important new information about a marketed product that should be directed to all health care providers who are likely to prescribe, dispense, or administer the drug, as well as others who need to know the disseminated information. In most cases, the information relates to an important safety concern that could affect prescribing decisions, patient counseling, or in some cases, contacting patients immediately who may need to alter their behavior (e.g., switch medications or discontinue treatment).

Individual health care providers may use the information included in this information collection to make decisions about what products to prescribe for their patients, and how to counsel patients about their medications.

3. Use of Improved Information Technology and Burden Reduction

Although FDA regulations at § 200.5 focus on paper mailings of DHCP letters, the guidance makes it clear that the recommendations apply to electronic communications as well (e.g., distribution by e-mail or made available on the Internet on company websites). FDA believes that approximately 50% of manufacturers and distributers are currently using information technology to distribute DHCP letters.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

While the information collection provisions apply to small and large businesses alike, FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

This information collection will occur strictly as it is needed based on how data evolve and information emerges (e.g., important new safety information that concerns a significant health hazard of a marketed product) since new or updated information about a drug product emerges throughout a product's life cycle. Collecting the information with any less frequency (e.g., annual or biennial updates, or every decade) would result in health care providers lacking timely information crucial to patient care. Timeliness of drug safety information is fundamental for its usefulness and anything less than as-needed frequency could be potentially catastrophic for patients.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of March 10, 2016 (81 FR 12734). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided for the information collection.

10. Assurance of Confidentiality Provided to Respondents

Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by Section 301(j) of the FD&C Act, and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of respondents: Respondents to the collection of information are manufacturers and distributors of drug for which the issuance of a *Dear Healthcare Provider* Letter is required under 21 CFR part 200.5.

12 a. Annualized Hour Burden Estimate

Based on a query of the FDA Document Archiving, Reporting, and Regulatory Tracking System, FDA estimates that approximately 25 DHCP letters will be submitted annually from approximately 18 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

FDA estimates the annual third-party disclosure burden as follows:

Table 1 – Estimated Annual Reporting/Third-Party Disclosure Burden[1]

21 CFR § 200.5	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure (Hours)	Total Hours
Mailing of Important Information About Drugs	18	1.40	25	100	2,500

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

12b. Annualized Cost Burden Estimate

FDA estimates an average manufacturer or distributor loaded wage rate of $110.13 per hour for preparing and submitting the information collection described in this guidance.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers and Distributors	100	$110.82	$11,082.00

Preparation of the DHCP letter requires clerical, medical, and legal input and review. Therefore, in valuing the time cost, FDA uses the weighted average of Pharmaceutical and Medicine Manufacturing (NAICS, Code 325400) industry-specific mean hourly wages for Office and Administrative Support Occupations ($20.66), Life, Physical, and Social Science Occupations ($36.02), Legal Occupations ($74.13), and Management Occupations ($67.66). FDA assigns these occupational categories weights of 10 percent, 30 percent, 30 percent, and 30 percent. The resulting composite wage in 2015 is $55.41 (= [$20.66 per hour * 0.10] + [$36.02 per hour * 0.30] + [$74.13 per hour * 0.30] + [$67.66 per hour * 0.30]). FDA then doubles this amount to $110.82 (= $55.41 per hour * 2) to account for benefits and any capital costs. (Source: U.S. Bureau of Labor Statistics, "*Occupational Employment Statistics: May 2015 National Industry-Specific Occupational Employment and Wage Estimates NAICS 325400—Pharmaceutical and Medicine Manufacturing*," available at http://www.bls.gov/oes/current/naics4_325400.htm, March 30, 2016.)

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate a total annual cost to the Federal government of **$22,000** for the information collection. Letters that concern a significant hazard to health or that change important drug package labeling include FDA review to ensure they appropriately describe the safety concern, labeling change(s), and/or correction of labeling/advertising necessary, and also to ensure the letter is not false, misleading, or promotional, and finally to give other feedback to respondent we feel necessary. The grade level of staff performing these tasks ranges from GS-13 to GS-15 and takes at most 16 hours (i.e., combined hours of all disciplines involved) to complete. We receive approximately five to ten DHCP letters per year for an annual cost of $9,775. For letters concerning a correction of prescription drug advertising or labeling this includes approximately 15 hours of drafting letters by GS-13 or GS-14 staff and 5 hours of review for an annual cost of $12,225.

15. Explanation for Program Changes or Adjustments

The information collection shows a decrease. Because our records reflect there have been **7** fewer respondents to the collection, we have adjusted the corresponding number of annual burden hours by **500** and responses by **5**.

16. Plans for Tabulation and Publication and Project Time Schedule

The reporting requirements contained in this proposal will not be published, tabulated or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.