Guidance for Industry and FDA Staff - Dear Health Care Provider Letters: Improving Communication of Important Safety Information

0910-NEW

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." The Food and Drug Administration (FDA) regulations at § 200.5 (21 CFR 200.5) outline the general provisions for Dear Health Care Provider (DHCP) letters to be sent regarding important drug warnings, important prescribing information, and important correction of drug information, but do not provide instructions on the format and content of the actual letter. FDA requests OMB approval of the information collection burden to assist manufacturers and distributors in determining when a DHCP letter may be necessary or useful, and offers recommendations on the format and content of those letters. The guidance recommends that the target audience for DHCP letters include the full range of health care providers who may prescribe, dispense, or administer drugs. The guidance does not expand the scope of the audience for the letters; it clarifies the regulation and reflects the realities of today's healthcare system that has a variety of practitioners involved in patient care.

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 email 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. The guidance specifically refers to an earlier guidance for industry entitled "Using Electronic Means to Distribute Certain Product Information (71 FR 26102, May 3, 2006). That guidance referred to previously approved collections of information found in FDA regulations that are subject to review by OMB. The collections of information in that guidance is approved under OMB control number 0910-0249.

4. Efforts to Identify Duplication and Use of Similar Information

   The information collection imposes a burden that is not duplicative of any comparable requirement imposed by government or industry, to FDA's knowledge. Similar information is not available to FDA.

5. Impact on Small Businesses or Other Small Entities

   The recommendations of this guidance apply equally to all manufacturers and distributors of marketed products regarding the mailing of important information about drugs described in FDA regulations at § 200.5. FDA believes that its responsibility requires the equal application of the regulations to all businesses. While FDA does not believe it can apply different standards with respect to regulatory requirements, FDA does provide special help to small businesses. A small business coordinator has been assigned to the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep FDA management apprised of how regulatory decisions might impact the small business community. To provide additional assistance to small businesses, FDA has established an office whose exclusive concern is to provide small business with help in dealing with FDA regulatory requirements.

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 11/12/2010 (75 FR 69449). Thirteen public comments were received during the comment period and in ten of the letters the following two issues were raised. However, the other three comments did not address the information collection.

   (Comment): Section V of the draft guidance states that the target audience should be all health care providers who could not only prescribe the drug, but who could also dispense or administer the drugs. The comments call this an expansion of the target audience which would require manufacturers to send DHCP letters to physicians, nurses, pharmacists, and other prescribing and non-prescribing providers. Manufacturers would also need to seek out lists of such non-prescribing healthcare providers proactively and disseminate the letters more broadly than to just physicians. A recommendation was made to limit the letters to prescribers only.

   (Response): The regulation requires manufacturers and distributors to mail important information to "physicians and others responsible for patient care". (21 CFR 200.5) To the extent this includes non-prescribing healthcare professionals responsible for patient care the manufacturers should send letters to relevant personnel. This is not an expansion of the scope of the letters, merely a clarification of the regulation and a reflection of the healthcare system today that has a variety of practitioners involved in patient care.

   (Comment): In Section VI of the draft guidance, FDA recommends that companies conduct an evaluation of the extent to which the target audience received the DHCP letter and is aware of the information that was communicated in the letter. It also asked manufacturers to assess the impact of DHCP letters and their impact on patient behavior. Comments found this overly burdensome, beyond the Agency's statutory authority, and an unnecessary increase in correspondence, thereby potentially diluting the impact of the DHCP letters.

   (Response): We agree with the comments. The final guidance has been modified to suggest that manufacturers conduct an evaluation, *for their own use*, of the utility of the letters and their success in reaching the target audiences.
9. Explanation of Any Payment or Gift to Respondents

   No remuneration is provided.
10. Assurance of Confidentiality Provided to Respondents

    No sensitive information is sought in this guidance.
11. Justification for Sensitive Questions

    There are no questions of a sensitive nature.
12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Based on a review of MedWatch Safety Alerts, FDA identified each DHCP letter sent and the identity of each sponsor sending out a DHCP letter for each year. FDA estimates that approximately 30 DHCP letters will be received annually from approximately 25 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 Third-Party Disclosure Burden

21 CFR § 200.5	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Mailing of Important Information About Drugs	25	1.20	30	100	3000

12b. Annualized Cost Burden Estimate

FDA estimates an average manufacturer or distributor loaded wage rate of $105.61 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	$105.61	$10,561.00

Preparation of the DHCP letter would require 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 ($20.73), Life, Physical, and Social Science Occupations ($35.77), Legal Occupations ($70.96), and Management Occupations ($62.38). FDA assigns these occupational categories weights of 10 percent, 30 percent, 30 percent, and 30 percent. The resulting composite wage in 2012 is $52.81 (= [$20.73 per hour * 0.10] + [$35.77 per hour * 0.30] + [$70.96 per hour * 0.30] + [$62.38 per hour * 0.30]). FDA then doubles this amount to $105.61 (= $52.81 per hour * 2) to account for benefits and any capital costs. (Source: U.S. Bureau of Labor Statistics, "Occupational Employment Statistics: May 2012 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, July, 24 2013.)

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

    When manufacturers or distributors prepare DHCP letters that concern a significant hazard to health or to change important drug package labeling, they send the letters to FDA for review before the letters are sent to the health care providers. FDA staff analyze the letters to make sure the letters appropriately describe the safety concern, labeling changes, and/or correction of labeling/advertising and ensure that the letter is not false, misleading, or promotional and provide any comments to the applicant. The grade level of the staff who perform these reviews ranges from a GS-13 to a GS-15 and it takes 8-16 hours cumulative (i.e., combined hours of all disciplines involved) to complete the review. The FDA estimates that we receive five to ten DHCP letters per year. The annual cost to the Federal government is approximately$9,488.00, depending on how many letters are received for review and the grade level of the staff providing the review.

    FDA staff from the Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, sometimes prepare DHCP letters concerning a correction of prescription drug advertising or labeling. The grade level drafting these letters is a GS-13 or GS-14 and it is estimated to take 15 hours to complete. A GS-14 reviewer spends about 5 hours on reviewing the letter. This is estimated to cost the Federal government approximately $10,000 annually if five to ten DHCP letters are prepared.

    The total annualized cost to the government to prepare and review the DHCP letters is estimated at $19,488.

15. Explanation for Program Changes or Adjustments

    This is a new collection of information.

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

    We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.