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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. FDA–2008–N–0546]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of MedWatch^{Plus} Portal and Rational Questionnaire to collect electronically all adverse event, consumer complaint/product problem and medication use error data submitted to FDA.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All

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comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire—21 CFR 310.305, 314.80, 314.98, 514.80, 600.80, 1271.350 and Part 803

FDA is implementing electronic data collection to improve adverse event reporting across the agency. FDA's current processes and systems for adverse event reporting vary across its centers and are not optimal for the efficient collection of voluntary and mandatory adverse event reports, product problems/consumer complaints, or errors associated with the use of FDA-regulated products. Current FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are an outgrowth of a paper process era and frequently result in the submission of inconsistent and poor quality information. In addition, the agency is limited in its ability to modify its paper forms to keep pace with changes in the types of regulated products and the information necessary to meet evolving standards to ensure post market safety. Further, the existing supporting business processes are not able to efficiently manage the information being provided on the paper forms. For example, the upfront data integrity constraints on required (vital) data limit the extent of reviewable information on items such as reporter identification of one or more subject product types (animal and human food/feed, drug - animal or human, device, etc.), reporter name, date of occurrence, related details, and follow-up information. Data collected on paper forms must be manually transcribed into an electronic format for usability and analysis. Furthermore, these forms are not very intuitive for a casual reporter (e.g., consumers of FDA-regulated products), that is, the paper forms lack the features available in an electronic system that assist a new user in understanding what information is being requested.

FDA has launched the development and implementation of a new electronic system for collecting, submitting and processing adverse event reports and other safety information for all FDA-regulated products. This new system, MedWatch^{Plus} Portal, will enhance the current MedWatch collection system and integrate the agency's existing safety reporting systems into the various FDA Adverse Event Report Systems (FAERS). FAERS will enable FDA staff to more efficiently analyze thousands of safety reports and to identify potential safety problems earlier than would be possible using paper forms. The MedWatch^{Plus} Portal provides one central point-of-entry for persons submitting information to FDA. The agency believes that one central point-of-entry will better enable persons to submit their information. In addition, mandatory reporters will be able to use the Internet to access the MedWatch^{Plus} Portal to report safety concerns about dietary supplements, nonprescription drugs, and human and animal food, thus fulfilling the mandatory reporting requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109–462) and the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85).

The MedWatch^{Plus} Portal involves the development of a single Web-based portal and a user-friendly data collection tool, the "Rational Questionnaire," which will make it easy for anyone to report a safety problem. The Rational Questionnaire will ask users simple questions to help guide them to determine what information they should provide. Anyone will be able to use the questionnaire to submit adverse event, product problem/consumer complaint, and medication use error reports to the FDA. For example, a healthcare practitioner could report an adverse event; a medical device maker could report a safety concern about a product; a pet owner could report a problem

that their pet experienced associated with the use of an animal drug or animal food; a parent could report a reaction that their child experienced associated with the use of a cosmetic; and a consumer could report a concern about a drug they are taking at home, or about a food that may have made them ill. The system will compile the users' responses into a standardized report that would be routed to the appropriate FDA organizational component(s) for review and analysis.

There are several types of information that will be submitted to FDA via the MedWatch^{Plus} Portal and Rational Questionnaire. Some of the information is required to be submitted to FDA (mandatory reporting) and some of the information is submitted voluntarily (voluntary reporting). The majority of the information to be collected using the MedWatch^{Plus} Rational Questionnaire has been approved previously by OMB under the Paperwork Reduction Act. Recently, additional information collection has been mandated by DSNDCPA and FDAAA. A complete list of information collections, their current OMB approval numbers, as well as citations to the relevant statute, regulation or guidance information for each is depicted in table 1 of this document.

TABLE 1.—INFORMATION COLLECTIONS

FDA Center	FDA Form No.	OMB No.	Relevant Statute, Regulation or Guidance Information	Mandatory (M) or Voluntary (V)
CBER/CDER	3500	0910–029	MedWatch Form FDA 3500, Voluntary Reporting Instructions.	V
CBER/CDER	3500A	0910–0291	21 CFR 310.305, 314.80, 314.98, 600.80 and 1271.350.	M
CDRH	3500	0910–0291	MedWatch Form FDA 3500, Voluntary Reporting Instructions.	V
CDRH	3500A	0910–0291	21 CFR Part 803	M
CFSAN	3500	0910–0291	None	V

TABLE 1.—INFORMATION COLLECTIONS—Continued

FDA Center	FDA Form No.	OMB No.	Relevant Statute, Regulation or Guidance Information	Mandatory (M) or Voluntary (V)
CFSAN*	3500A	OMB approval is in process.	Pub. L. 109–462; Section 761(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379aa–1(b)(1)).	M
CFSAN/CVM*	None	This notice solicits comments on this proposed new collection.	Pub. L. 110–85; Section 417 of the Act (21 U.S.C. 350(f)).	M
CVM	1932a	0910–0284	Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report Form and Instructions.	V
CVM	1932	0910–0284	21 CFR 514.80	M
CVM*	None	This notice solicits comments on this proposed new collection.	Pub. L. 110–85; Section 1002 of FDAAA.	V
ORA	None	This notice solicits comments on this proposed new collection.	None	V

*New reporting requirements included in DSNDCPA and FDAAA.

The single portal and a harmonized, Web-based format for submitting safety information will greatly enhance the ability of FDA to protect the public health. FDA will analyze electronic adverse event and safety reports for all marketed products and track safety signals throughout the life cycle of FDA-regulated products. FDA intends to review the information the agency receives to ensure that the submitters comply with the criteria established by the Federal Food, Drug, and Cosmetic Act (the act), where required.

Description of respondents: The respondents to this collection of information include all persons submitting mandatory or voluntary information electronically to FDA via the MedWatch^{Plus} Portal and Rational Questionnaire.

FDA expects that all of its centers and the Office of Regulatory Affairs (ORA) will be utilizing the electronic reporting capabilities of MedWatch^{Plus}

Portal by Fiscal Year 2011. Thus, FDA has prepared its estimate of the annual reporting burden on the basis that the majority of all submissions will be submitted electronically.

FDA estimates the burden of this information collection as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Voluntary View	37,565	1	37,565	0.6	22,539
Mandatory View using MedWatch^{Plus} Rational Questionnaire[2]	645	199	128,403	1.0	128,403
Mandatory View using direct Gateway-to-Gateway transmission[2]	2,578	199.2	513,613	0.6	308,168
Reportable Food (human and animal) Mandatory View	1,200	1	1,200	0.6	720
Reportable Food (human and animal) Voluntary View	1,200	1	1,200	0.6	720
Early Warning Recall Voluntary View	540	1	540	0.6	324
Total					460,874

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.[2] The reporter may choose to use the MedWatch^{Plus} Rational Questionnaire or a direct Gateway-to-Gateway transmission to submit a Mandatory report. FDA believes that these are different reporting burdens for these two types of transmission of information. The reporting burden for use of the MedWatch^{Plus} Rational Questionnaire Mandatory View is estimated to be 1 hour. The reporting burden for a direct Gateway-to-Gateway transmission is estimated to be 0.60 hours. Current reporting estimates indicate that approximately 80% of the Mandatory Reports would be submitted via a Gateway-to-Gateway transmission and 20% of reports would be received via the MedWatch^{Plus} Rational Questionnaire in the future. The Mandatory View reporting burden estimates reflect this calculation.

The term "Voluntary View" refers to the MedWatch^{Plus} Rational Questionnaire as it appears to a respondent submitting a voluntary report. The term "Mandatory View" refers to the Gateway-to-Gateway and the MedWatch^{Plus} Rational Questionnaire as it appears to a respondent submitting a mandatory report. The estimated number of responses and hours per response for the voluntary view and the mandatory view are based on FDA's experience and the average number of voluntary reports and mandatory reports submitted to FDA in 2007 (and in the case of mandatory dietary supplement reports, those submitted to FDA from January 1, 2008 to April 15, 2008) via the existing methods of submission, including paper submission. The term, "Reportable Food (human and animal) Mandatory View" refers to the MedWatch^{Plus} Rational Questionnaire as it appears to a respondent submitting a mandatory report under section 417 of the act. The term, "Reportable Food

(human and animal) Voluntary View" refers to the MedWatch^{Plus} Rational Questionnaire as it appears to the respondent submitting a voluntary report under section of 417 of the act. The estimated number of responses and hours per response for the reportable food (human and animal) mandatory and voluntary views are based on FDA's experience with reports recently submitted to FDA that would be considered "Reportable Food" reports in the future. The term, "Early Warning Recall Voluntary View," refers to the MedWatch^{Plus} Rational Questionnaire as it appears to a respondent submitting a mandatory report under FDAAA Section 1002 of the act (Pub. L. 110–85). The estimated number of responses and hours per response for the early warning recall voluntary view are based on FDA's experience with reports recently submitted to FDA that would be considered "Early Warning Recall" reports in the future.

In an effort to meet the needs of all reporters, the Rational Questionnaire will allow for the submission of a report by completing certain minimum data elements. Both mandatory and voluntary reporters will see and be provided the opportunity to submit additional optional information. A Reporter can answer one, a few, or all of the optional questions. Reporters are strongly encouraged to submit as much optional information as possible. This will help to ensure the FDA has sufficient information to identify products and problems, and enhance their ability to address these problems.

The optional questions serve a purpose for both the Reporter and the FDA. The Reporter may believe that additional information is needed for FDA to fully understand the event/problem and the optional questions provide an opportunity to provide such information. For the FDA, the optional questions may aid in fully understanding the problem and may eliminate the need for extensive follow up with the Reporter. Because Reporters can choose to answer

none, one, a few, or all of the optional questions, we estimated the maximum time needed to submit a safety report online for both voluntary and mandatory reporters in the hours per response column in table 2 of this document.

The agency's estimate of the number of respondents and the total annual responses in table 2 is based on the mandatory and voluntary reports submitted to the centers and ORA. The estimated total annual responses in table 2 are based on initial reports. Follow-up reports, if any, are not counted as new reports. FDA estimates that it will receive 37,565 voluntary reports [23,033 (CBER/CDER) + 4,369 (CDRH) + 5,000 (CFSAN) + 163 (CVM) + 5,000 (ORA) = 37,565]. FDA estimates that it will receive 642,016 mandatory reports [459,121 (CBER/CDER) + 146,274 (CDRH) + 856 (CFSAN) + 35,765 (CVM) + 0 (ORA) = 642,016].

FDA received 23,033 voluntary reports to CBER/CDER during 2007. Based on this experience, FDA estimates that CBER and CDER, collectively, will receive 23,033 voluntary reports annually from 23,033 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours, for a total burden of 13,820 hours (23,033 reports x 0.6 hours = 13,819.8 hours).

FDA received 459,121 mandatory reports to CBER/CDER during 2007. Based on this experience, FDA estimates that CBER and CDER, collectively, will receive 459,121 mandatory reports annually from 600 users of the electronic reporting system. FDA estimates the maximum reporting burden for a mandatory report to be 1 hour, for a total burden of 459,121 hours ((459,121 reports x 1 hour) or a minimum burden of 312,202 hours with ((459,121 reports x 80% x 0.60 hour) + (459,121 reports x 20% x 1 hour) = 312,202.28 hours).

FDA received 4,369 voluntary reports to CDRH during 2007. Based on this experience, FDA estimates that CDRH will receive 4,369 voluntary reports annually from 4,369 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours, for a total burden of 2,621 hours (4,369 reports x 0.6 hours = 2,621.4 hours).

FDA received 146,274 mandatory reports to CDRH during 2007. Based on this experience, FDA estimates that CDRH will receive 146,274 mandatory reports annually from 1,665 users of the electronic reporting system (a group comprised of facilities, importers, and manufacturers). FDA estimates the maximum reporting burden for a mandatory report to be 1 hour, for a total burden of 146,274 hours (146,274 reports x 1 hour = 146,274 hours) or a minimum burden of 99,466 hours with ((146,274 reports x 80% x 0.60 hour) + (146,274 reports x 20% x 1 hour) = 99,466.32 hours). FDA received 5,000 voluntary reports to CFSAN during 2007. Based on this experience, FDA estimates that CFSAN will receive 5,000 voluntary reports annually from 5,000 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours, for a total burden of 3,000 hours (5,000 reports x 0.6 hours = 3,000 hours).

FDA received 214 mandatory dietary supplement reports to CFSAN from January 1, 2008, to April 15, 2008. Based on this experience, FDA estimates that CFSAN will receive 856 mandatory reports annually from 150 users of the electronic reporting system. FDA estimates the maximum reporting burden for a mandatory report to be 1 hour, for a total burden of 856 hours (856 reports x 1 hour = 856 hours) or a minimum burden of 582 hours with ((856 reports x 80% x 0.60 hour) + (856 reports x 20% x 1 hour) = 582.08 hours).

FDA received 163 voluntary reports to CVM during 2007. Based on this experience, FDA estimates that CVM will receive 163 voluntary reports annually from 163 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours for a total burden of 98 hours (163 reports x 0.6 hours = 97.8 hours).

FDA received 35,765 mandatory reports to CVM during 2007. Based on this experience, FDA estimates that CVM will receive 35,765 mandatory reports annually from 808 users of the electronic reporting system. FDA estimates the maximum reporting burden for a mandatory report to be 1 hour, for a total burden of 35,765 hours (35,765 reports x 1 hour = 35,765 hours) or a minimum burden of 24,320 hours with ((35,765 reports x 80% x 0.60 hour) + (35,765 reports x 20% x 1 hour) = 24,320.20 hours).

FDA received 5,000 voluntary reports to ORA during 2007. Based on this experience, FDA estimates that ORA will receive 5,000 voluntary reports annually from 5,000 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours, for a total burden of 3,000 hours (5,000 reports x 0.6 hours = 3,000 hours). ORA does not receive mandatory reports.

FDAAA, Section 1005, the Reportable Food Registry, established new electronic mandatory and voluntary reporting requirements for instances of "reportable" food, meaning an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA received 625 voluntary food complaints leading to adverse events from January 1, 2008, to June 30, 2008, and there were 206 and 182 Class 1 Recalls for human food in Fiscal Years 2006 and 2007,

respectively. Based on these experiences, FDA estimates that FDA could receive 200 to 1,200 "reportable" food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. FDA will utilize the upper-bound estimate of 1,200 for these calculations. FDA estimates the reporting burden for a mandatory "reportable" food report to be 0.6 hours, for a total burden of 720 hours (1,200 reports x 0.6 hours = 720 hours). FDA estimates the reporting burden for a voluntary "reportable" food report to be 0.6 hours, for a total burden of 720 hours (1,200 reports x 0.6 hours = 720 hours).

FDAAA, Section 1002, Early Warning Recall, mandated the FDA establish a system to receive voluntary pet food complaint reports and provide an Early Warning Recall system for the public. FDA received 270 voluntary pet food reports from January 1, 2008 to June 30, 2008. FDA received 10,740 and 99 pet food complaints in FY 2007 and 2006, respectively. Based on these experiences, FDA estimates that FDA could receive 540 voluntary pet food reports annually from 540 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary "Early Warning Recall" report to be 0.6 hours, for a total burden of 324 hours (540 reports x 0.6 hours = 324 hours).

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: 10/16/08

October 16, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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