Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department of Health and Human Services is committed to ensuring that women, minority groups, and physically challenged individuals are adequately represented on the Committee. Nominations of qualified candidates from these categories are encouraged. The Department also seeks to have geographic diversity reflected in the composition of the Committee.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: May 14, 2009.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E9–11675 Filed 5–19–09; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Extension to HS Transportation Requirement.

OMB No.: 0970–0260.

Description: The Office of Head Start is proposing to renew authority to collect information regarding the Head Start transportation requirement without changes. The transportation requirement provides the requirement that each child be seated in a child restraint system while the vehicle is in motion, and the requirement that each bus have at least one bus monitor on board at all times. Waivers would be granted when the Head Start or Early Head Start grantee demonstrates that compliance with the requirement(s) for which the waiver is being sought will result in a significant disruption to the Head Start program or the Early Head Start program and that waiving the requirement(s) is in the best interest of the children involved.

Respondents: Head Start and Early Head Start program grants recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form	275	1	1	275

Estimated Total Annual Burden Hours: 275.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: May 14, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–11652 Filed 5–19–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0546]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 19, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire

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 followup 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) (Public Law 109–462) and the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 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 PRA. 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)
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research (CBER/CDER)	3500	0910–0291	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
Center for Devices and Radiological Health (CDRH)	3500	0910–0291	MedWatch Form FDA 3500, Voluntary Reporting Instructions	V
CDRH	3500A	0910–0291	21 CFR Part 803	M
Center for Food Safety and Applied Nutrition (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[1]	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/Center for Veterinary Medicine (CVM)[1]	None	This notice solicits comments on this proposed new collection	Pub. L. 110–85; Section 417 of the act (21 U.S.C. 350f)	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[1]	None	This notice solicits comments on this proposed new collection	Pub. L. 110–85; Section 1002 of FDAAA	V
Office of Regulatory Affairs (ORA)	None	This notice solicits comments on this proposed new collection	None	V

[1] 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 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.

In accordance with 5 CFR 1320.8(d), in the **Federal Register** of October 23, 2008 (73 FR 63153), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received five letters in response to the four specified aspects of the collection of information, each containing one or more comments.

(Comment 1) Several comments commended FDA for implementing electronic data collection to improve adverse event reporting and expected the new format to greatly improve the agency's ability to utilize adverse event, product problem/consumer complaints, and medication use error reports submitted to FDA.

(Response) FDA agrees. As discussed previously in this document, the new system will enhance the current MedWatch collection system and integrate the Agency's existing adverse event reporting systems. This 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.

(Comment 2) One comment recommended that FDA continue to allow the submission of adverse event reports via paper. Another comment requested that FDA allow for a paper based contingency in the event that the MedWatch^{Plus} system becomes unavailable.

(Response) FDA agrees. The agency is not eliminating paper, or telephone reporting. We will continue to support and accept reports submitted to us by mail, fax or telephone including when the system is unavailable.

(Comment 3) One comment stated that FDA should recognize that the major component of the reporting burden is in the assembly of data, not in the transmission of data. The comment suggested that the submission of mandatory data to the MedWatch system will take 1 hour per initial report and from one-half hour to 3 hours for supplemental reports.

(Response) FDA agrees that the assembly of data is a major component of the reporting burden. However, the agency notes that the comment did not provide any data to support the burden hour figures set forth. Thus, FDA has not changed the burden hour estimates in tables 1 and 2 of this document.

(Comment 4) Several comments suggested that FDA consider using pilot programs in the different stages of developing the system. One comment suggested using a pilot with the proposed questionnaire. Another comment asked FDA to consider developing a pilot project with electronic medical record software vendors to assess the functionality and determine the impact on the practitioner's time to complete the submission. A third comment offered to provide the assistance of its professional association members to assess the functionality of the MedWatch^{Plus} portal and rational questionnaire.

(Response) FDA agrees. The agency intends to utilize internal and external early adopters for user acceptance testing that will include a test site environment for beta testing prior to implementation of the portal. However, the integration of electronic medical record software is not in scope for the planned releases of MedWatch^{Plus} portal and rational questionnaire.

(Comment 5) One comment expressed concern that those wanting to use the Web portal would not be able to find it.

Another comment suggested that FDA initiate a public education campaign to ensure potential users are aware of the new system and use the new system correctly.

(Response) FDA agrees and is working with National Institutes of Health and the FDA Internet teams to follow the HHS Internet guidelines for Web design. We expect that the link to the MedWatch^{Plus} portal and rational questionnaire will be prominently displayed on the FDA home page. FDA also intends to reach out to our industry stakeholders, as well as professional organizations and community interest groups. The rational questionnaire will provide the user with detailed navigation instructions to include drop-down menus, lists of values and controlled vocabularies where possible. In addition, FDA will issue guidance and technical documents for the iterative releases of the rational questionnaire. The FDA intends to provide a phased approach. The first release will include Reportable Food Reports. Early Warning Pet Food Recall and adverse event reports for veterinary drug products will follow. Other product reports (CFSAN, CVM, CDER, CBER and CDRH) will be rolled out in later releases.

(Comment 6) One comment suggested that FDA include a means by which adverse events associated with other products could be reported using the MedWatch^{Plus} portal and rational questionnaire, including: devices used in animals, compounded drugs for animals, and biologics used in animals.

(Response) FDA agrees that individuals should be able to report adverse events associated with devices used in animals and adverse reactions associated with compounded drugs for animals. For example, when the MedWatch^{Plus} portal is operational, reporters will be able to use the animal adverse event view of the rational questionnaire to submit these reports. Furthermore, adverse event reports submitted through the portal for biologic products used for animals will be forwarded to the U.S. Department of Agriculture.

(Comment 7) One comment suggested that the Naranjo scale be incorporated into the rational questionnaire.

(Response) FDA disagrees. The Naranjo scale is a causality assessment tool. FDA does not plan to require assessment of causality by reporters who already suspect a product-event association and have made the decision to report by accessing the MedWatch^{Plus} portal.

(Comment 8) One comment suggested that FDA should adjust its business processes to effectively leverage and appropriately respond to rapidly changing data in terms of number of reports, varying quality, and potential impact to signal detection.

(Response) FDA agrees. The rational questionnaire will facilitate the collection of consistent, complete, accurate information and produce a structured report utilizing the HL7–ICSR data exchange message. The agency will continue to support the submission of ''batched'' adverse event reports through the FDA electronic submission gateway. FDA is moving toward the use of the HL7–ICSR message exchange; however, acceptable, alternative data exchange message formats (e.g., E2BM, E2BR) will be supported for a period of time that has not been yet been determined.

(Comment 9) One comment suggested that the MedWatch^{Plus} portal and rational questionnaire should document who submits the information and stated that the type of submitter (e.g., pharmacist, physician, patient) provides a good indication of the accuracy of and the reasons behind the information provided.

(Response) FDA agrees that information describing the type of submitter is useful. The rational questionnaire reporting views will be created to include questions describing who the reporter is, the type of report (adverse event, product problem/consumer complaint or product use error), whether the reporting is mandatory, and identify the suspect product. From that information, the agency can infer the type of submitter as follows: General citizen, health care professional, and whether or not the reporter is a mandatory or voluntary reporter.

(Comment 10) One comment recommended that FDA obtain contact information from all individuals who submit adverse event reports, arguing that false reports could be submitted more readily if individual contact submission is not required for report submission. The comment also noted that such information would allow FDA to follow up with individuals and verify reported information in the event that FDA had questions or concerns regarding an individual report.

(Response) FDA is encouraging all users to provide contact information in all reports which both verifies the source of the report and allows FDA to conduct any needed followup. However, FDA will accept voluntary reports submitted by anonymous sources. Only mandatory reporters will be required to include their contact information.

(Comment 11) One comment urged FDA to consider how duplicate reporting through different mechanisms will be reduced or eliminated.

(Response) FDA agrees. We have a system requirement that addresses our abilities to assess and link duplicate reports to minimize the problem of duplicate reporting. In addition, the Web portal will allow followup information as well as attachments to be entered and linked to a previously submitted report.

(Comment 12) One comment suggested that FDA should incorporate the Alternative Summary Report (ASR) methodology in MedWatch^{Plus}.

(Response) FDA is considering including summary reporting (ASRs) in future releases of the rational questionnaire, but the exact mechanism has not been determined.

(Comment 13) The rational questionnaire should not have supplemental questions, which are not required by the agency's regulations at 21 CFR Part 803.

(Response) The rational questionnaire will include the information mandated by regulation, legislation or otherwise deemed necessary by the agency for a complete report. Reporters will not be required to submit information in response to optional questions.

(Comment 14) One comment recommended that a single acknowledgement bearing the MDR report number and the official time receipt stamp be transmitted to the sender within one hour of the MDR submission. Another comment noted that the FDA 3500A form is the evidentiary record of the MDR. The comment went on to express concern about how the MedWatch^{Plus} system would acknowledge the submission of the adverse event report in the required timeframe.

(Response) FDA agrees. The reporter will receive an electronic response with an acknowledgement containing a unique FDA identification number, which the reporter can save and print. The acknowledgement receipt will be generated immediately by the MedWatch^{Plus} system. The reporter may also print and save an electronic copy of their report. If the reporter creates an account, the reporter will have access, for an undetermined finite period of time, to both their in-process and previously submitted reports using the MedWatch^{Plus} system. However, FDA notes that voluntary reporters who report anonymously will not receive such a response because we will not have their email address, but they will be able to print and save an electronic copy of their report.

(Comment 15) One comment asked that FDA engage stakeholders in a public consultation process and asked FDA to subject a draft of the rational questionnaire to a public consultation period to permit manufacturers, patients, and other stakeholders to comment prior to finalizing a questionnaire for production use.

(Response) FDA agrees. We plan to use internal and external stakeholders in user acceptance testing. Additionally, the agency intends to hold two public meetings for Reportable Foods and give presentations on the Web-based portal and the rational questionnaire at professional organization and industry meetings.

(Comment 16) One comment suggested that FDA make the electronic collection tool user friendly and asked that the questionnaire be made accessible and intuitive for a broad population to use, with easy to understand data entry instructions and a user-friendly interface that requires limited computer or technical expertise to complete. Another comment stated that the effectiveness of the rational questionnaire would depend on the length of time required for the user to complete the adverse event report.

(Response) FDA agrees that the rational questionnaire should be user friendly. We are taking every available step in developing this tool to ensure that it is user-friendly and accessible for public use while minimizing user time. Such steps include utilizing both internal and external expertise with Web-techniques and leveraging current technology. The agency is following HHS Web standards in developing the portal and rational questionnaire and plans to collect feedback during the user acceptance testing.

(Comment 17) Another comment suggested that questions on the rational questionnaire should be prioritized to capture the most important questions and information first in a shorter period of time. Another comment suggested that FDA should use an electronic approach that will ensure that reporters only see and fill out those fields relevant to the event that they are reporting.

(Response) FDA agrees that the questions should be prioritized. The rational questionnaire is designed to request the mandatory information first, then present the optional questions. In addition, the specific reporting situations will use a tree-branching logic approach. The reporter will be provided only those fields necessary to providing a full report and they will not see questions that are not needed, which helps in prioritizing the information.

(Comment 18) One comment suggested that FDA create an intelligent questionnaire that aligns with the reporter's knowledge base and experience. Another comment requested that FDA provide an advanced method of submitting information using the rational questionnaire that would allow individuals familiar with the system to more quickly and efficiently input the information.

(Response) FDA agrees. FDA is aware that persons familiar with the reporting process do not want to be led through the questionnaire because they know what information they want to report. The agency is planning future releases of the rational questionnaire with an ''Expert Reporter'' mode for those who are familiar with the information and frequent reporters. FDA notes that if a user chooses to establish an account with FDA, the system will be designed so that when the user properly signs in, the system will pre-populate the point-of-contact information. In addition, when a report is submitted, a user will be able to retain and save unique identifying information which can be used to access a previously filed report for additional followup reporting.

(Comment 19) One comment suggested that FDA ensure that the MedWatch^{Plus} portal is interoperable with software that institutions currently use to document suspected adverse drug events internally.

(Response) The MedWatch^{Plus} portal is available to all users through the Internet, without requiring the use of special software. The portal will also allow submission of attachments to reports in commonly-used file formats, such as Microsoft Word, Excel and Adobe. The agency intends to publish guidance that will provide a list of acceptable file types. In the event that a user would like to submit an attachment that is in an unacceptable file type, the agency intends to communicate with the user via a message providing instructions for file types we will accept and contact information for a help desk providing IT support and additional assistance to the public. The current MedWatch^{Plus} portal and rational questionnaire project scope does not include the integration with electronic medical record software, but may be considered in the future as medical software systems mature and are increasingly utilized.

(Comment 20) One comment asked FDA to ensure interoperability utilizing HL7 or other appropriate standards. Another comment asked FDA to utilize international consensus standards in electronic case reporting.

(Response) FDA agrees. The MedWatch^{Plus} rational questionnaire will produce an HL7–ICSR data exchange message and the portal will accept HL7–ICSR compliant exchange messages that are formatted outside the rational questionnaire. As noted previously in this document, the agency will continue to support the submission of 'batched' adverse event reports through the FDA electronic submission gateway. FDA is moving toward the use of the HL7–ICSR message exchange; however, acceptable, alternative data exchange message formats (e.g., E2BM, E2BR) will be supported for a period of time that has not been yet been determined. We intend to use structured and controlled vocabularies and terminologies where they exist.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Activity	Number 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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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 0.6 hours. Current reporting estimates indicate that approximately 80 percent of the Mandatory Reports would be submitted via a Gateway-to-Gateway transmission and 20 percent 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 (21 U.S.C. 350f). 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 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 (Public Law 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 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 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 FDA, the optional questions may aid in fully understanding the problem and may eliminate the need for extensive followup 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 of this document 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. Followup 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 0.6 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 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).

Dated: May 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A549 Cells: A Well-Characterized Lung Carcinoma Cell Line Utilized for a Variety of Scientific Studies, Including Adenovirus Production and Testing

Description of Technology: Scientists at the National Institutes of Health have developed a cell line designated A549 that was derived from explanted cultures of human lung cancer tissue. The A549 cell line has been tested under the guidance of the United States Food and Drug Administration (FDA) so, under current Good Manufacturing Practices (GMP), these cells may be suitable for use in manufacturing constructs for use in clinical trials. The A549 cell line has also been found to be suitable for adenovirus production, most notably replicating adenovirus constructs that do not require complementation by the viral oncogene, early region 1A (E1A), which is responsible for viral gene transcription. This cell line is further utilized as a negative control in assays to measure the replication of adenoviruses that lack E1A and as a target cell line to detect replication competent adenoviruses (RCA). A549 cells have been well characterized through their use in a wide variety of molecular studies, such as anti-tumor drug permeability and