ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Think Cultural Health Registration Form.	Physician	27477	1	3/60	1,373.85
	Nurse	44723	1	3/60	2,236.15
	Physician Assistant	1882	1	3/60	94.10
	Dentist	377	1	3/60	18.85
	Dental Professional	39	1	3/60	1.95
	Social Worker	1733	1	3/60	86.65
	Public Health	186	1	3/60	9.30
	General Healthcare Worker	12635	1	3/60	631.75
	Psychologist/Psychiatrist	189	1	3/60	9.45
	Mental Health Professional	180	1	3/60	9.00
	Pharmacist, RPH	750	1	3/60	37.50
	Emergency Medical Technician	492	1	3/60	24.60
	Administrator or Hospital Executive	151	1	3/60	7.55
	Policymaker or Public Official	17	1	3/60	0.85
	Teacher	424	1	3/60	21.20
	Lawyer	107	1	3/60	5.35
	Bachelors	3753	1	3/60	187.65
	Masters	4063	1	3/60	203.15
	Doctorate	1130	1	3/60	56.50
	Student	7504	1	3/60	375.20
	Other	10880	1	3/60	544.00
Total	118692	1	3/60	5,934.60	

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2012–17489 Filed 7–18–12; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort; Correction

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: HHS published a notice in the **Federal Register** (Volume 77, Number 130, Page 40059) on July 6, 2012 to give notice of a decision to designate a class of employees from the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. The designation was incorrect. Therefore, HHS has published this notice of correction. On June 27, 2012, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of DOE, its predecessor agencies, and their contractors, or subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1968 through December 31, 1978, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

The designation published in this notice of correction will become effective on July 27, 2012, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–17569 Filed 7–18–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0230]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Examination of Online Direct-to-Consumer Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Examination of Online Direct-to-Consumer Prescription Drug Promotion'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 31, 2012, the Agency submitted a proposed collection of information entitled ''Examination of Online Direct-to-Consumer Prescription Drug

Promotion'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0714. The approval expires on July 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17554 Filed 7–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0248]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

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.

DATES: Fax written comments on the collection of information by August 20, 2012.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0430. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

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.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level—(OMB Control Number 0910–0430)—(Extension)

This information collection approval request is for FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the Agency will interpret and apply provisions of the existing regulations regarding internal Agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (§ 312.48 (21 CFR 312.48)) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§ 314.103 (21 CFR 314.103)). In addition, the guidance provides information on how the Agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in 21 CFR parts 10, 312, and 314, establish procedures for the resolution of scientific and procedural disputes between interested persons and the Agency, CDER, and CBER. All Agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in part 312 (OMB control number 0910–0014), part 314 (OMB control number 0910–0001), and part 601 (21 CFR part 601) (OMB control number 0910–0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(11)(d), 314.50, 314.94, and 601.2) state that information provided to the Agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571—OMB control number 0910–0014, and FDA Form 356h—OMB control number 0910–0338.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the Agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the appropriate Agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution