

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. 2013-06844 Filed 3-25-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Battelle Laboratories King Avenue facility in Columbus, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On March 6, 2013, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the King Avenue facility owned by Battelle Laboratories in Columbus, Ohio, during the period from April 16, 1943, through June 30, 1956, 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.

This designation will become effective on April 5, 2013, 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. 2013-06846 Filed 3-25-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

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

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from the Hanford site in Richland, Washington, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On March 6, 2013, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All personnel who were internally monitored (urine or fecal), who worked at the Plutonium Finishing Plant in the 200 Area at the Hanford site, from January 1, 1987, through December 31, 1989.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (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. 2013-06849 Filed 3-25-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health

(NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from General Steel Industries in Granite City, Illinois, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On March 6, 2013, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All individuals who worked in any location at the General Steel Industries site, located at 1417 State Street, Granite City, Illinois, from January 1, 1953, through June 30, 1966, and/or during the residual radiation period from July 1, 1966, through December 31, 1992.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (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. 2013-06845 Filed 3-25-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

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 April 25, 2013.

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 0910-0331. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5733, *domini.bean@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.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93 (OMB Control Number 0910-0331)—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) requires that FDA be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6). Section 403(r)(6) of the FD&C Act requires that FDA be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and

accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The procedural regulation for this program is codified at 21 CFR 101.93. Section 101.93 provides submission procedures and identifies the information that must be included in order to meet the requirements of section 403 of the FD&C Act.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the **Federal Register** of January 18, 2013 (78 FR 4153), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice. One comment in the letter suggested that electronic submission could potentially decrease the reporting burden. FDA agrees and is in the process of developing a method of receiving submissions electronically.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93	2,200	1	2,200	0.75	1,650

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the FD&C Act in submitting information regarding section 403(r)(6) statements on labels or in labeling of dietary supplements. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403 of the FD&C Act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a submission, for a total of 1,650 hours (2,200 × 0.75). This estimate is based on the average number of notification submissions received by us in the preceding 3 years.

Dated: March 20, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
 [FR Doc. 2013-06823 Filed 3-25-13; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-P-0649]

Determination That QUESTRAN (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, and QUESTRAN LIGHT (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined

that QUESTRAN (cholestyramine for oral suspension, USP), equivalent to (EQ) 4 grams (g), and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug applications (ANDAs) that refer to these drugs, and it will allow FDA to approve ANDAs that refer to these drugs as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417)