September 30, 2013

The Honorable Joseph R. Biden, Jr.
President of the United States Senate
Washington, DC  20510

Dear Mr. President:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, to be added to the Special Exposure Cohort (SEC).

The Centers for Disease Control and Prevention’s (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petition and presented its findings to the Advisory Board on Radiation and Worker Health (Board) on July 17, 2012. The Board considered the petition, and on September 3, 2013, I received the Board’s recommendation concerning this petition. I have also received the deliberations, findings, and recommendations of the Director of NIOSH and the Director of CDC. Based on this information, I have designated the following class for addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1954, through December 31, 1967, 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 criteria and findings upon which this designation is based are provided in the enclosed report.

Please contact me if you have any further questions regarding this matter.

Sincerely,

[Signature on File]

Kathleen Sebelius

Enclosure
September 30, 2013

The Honorable Harry Reid  
Majority Leader  
United States Senate  
Washington, DC  20510

Dear Senator Reid:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, to be added to the Special Exposure Cohort (SEC).

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[Signature on File]

Kathleen Sebelius

Enclosure
September 30, 2013

The Honorable Mitch McConnell  
Minority Leader  
United States Senate  
Washington, DC  20510

Dear Senator McConnell:

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Sincerely,

[Signature on File]

Kathleen Sebelius

Enclosure
September 30, 2013

The Honorable Nancy Pelosi  
Minority Leader  
U.S. House of Representatives  
Washington, DC  20515

Dear Representative Pelosi:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, to be added to the Special Exposure Cohort (SEC).

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Sincerely,

[Signature on File]

Kathleen Sebelius

Enclosure
September 30, 2013

The Honorable John A. Boehner  
Speaker of the U.S. House of Representatives  
Washington, DC  20515

Dear Mr. Speaker:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, to be added to the Special Exposure Cohort (SEC).

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The criteria and findings upon which this designation is based are provided in the enclosed report.

Please contact me if you have any further questions regarding this matter.

Sincerely,

[Signature on File]

Kathleen Sebelius

Enclosure
HHS Designation of Additional Members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000

Designating a Class of Employees

Feed Materials Production Center (FMPC) 1954-1967

Fernald, Ohio
I. Designation

I, Kathleen Sebelius, Secretary of the Department of Health and Human Services (HHS), designate the class of employees defined in Section II of this report for addition to the Special Exposure Cohort (SEC), as authorized under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. § 7384q.

[Signature on File]______________              September 30, 2013________
Kathleen Sebelius    Date

II. Employee Class Definition

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1954, through December 31, 1967, 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.

III. Designation Criteria and Recommendations

Pursuant to 42 U.S.C. § 7384q, for the class defined in Section II of this report, the Secretary has determined, and the Advisory Board on Radiation and Worker Health (Board) has recommended, that

(1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and

(2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.

The SEC final rule states in 42 C.F.R. § 83.13(c)(1) that it is feasible in two situations to estimate the radiation dose that the class received with sufficient accuracy. First, the rule states that radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred under plausible circumstances by any member of the class. Alternatively, radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than a maximum dose estimate.

NIOSH determined that there is insufficient information to estimate the radiation doses that the class received with sufficient accuracy under the two abovementioned situations. The Board, pursuant to 42 U.S.C. § 7384q, advised the Secretary to designate the class as an addition to the SEC in a letter received by the Secretary on September 3, 2013.
IV. Designation Findings

Infeasibility of Estimating Radiation Doses with Sufficient Accuracy

The Secretary designates the class of employees covered by this report based upon the findings summarized below.

- The principal source of internal radiation doses for members of the proposed class were uranium and thorium.

- NIOSH previously determined that it has sufficient individual uranium bioassay data and a co-worker model to reconstruct the radiation dose resulting from internal uranium exposures for all Department of Energy (DOE) employees and DOE prime contractor employees during the time period from January 1, 1951, through December 31, 1983. Furthermore, NIOSH intends to use any internal uranium bioassay data that may become available for an individual claim (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures) to reconstruct the internal uranium dose for non-prime contractor employees who do not qualify for the SEC classes covering the time period from January 1, 1951, through December 31, 1983.

- The premise of NIOSH’s original proposal for reconstructing internal thorium exposures was to use Exposure Studies that characterized exposures to various job categories in each building using a time-weighted airborne radioactivity concentration value called a daily weighted exposure. However, later review revealed that the daily weighted exposure values were not representative of exposures exclusively from thorium operations. The Board also concluded that such a dose estimate was not sufficiently accurate because the dose reconstruction method being proposed could not have been based on plausible circumstances.

- NIOSH determined that members of this class may have received internal radiation exposures from working with uranium and thorium. Although it is feasible to reconstruct internal exposure to uranium for some workers, the Board concluded, and the NIOSH Director concurred, that NIOSH lacks sufficient information, which includes specific biological monitoring data, air monitoring information, process and radiological source information, and surrogate data from similar operations at other sites that would allow it to estimate the internal dose from exposures to thorium for any workers at FMPC from January 1, 1954, through December 31, 1967.

- The principal sources of external radiation doses for members of the proposed class include uranium, thorium, and their associated decay products, and transuranics (recycled uranium contaminants) that give rise to gamma, beta, and some neutron exposures.

- NIOSH has access to routine monitoring program data for measuring employees’ external radiation exposures to gamma and beta radiation and concluded it is feasible, using methods available in existing NIOSH procedures, to reconstruct external radiation doses for all FMPC workers for the period from January 1, 1954, through December 31, 1967.

- NIOSH concluded that the dose associated with medical x-ray exams, if required as a condition of employment and administered onsite, can be bound by using information in the Technical Basis Document of the Fernald Environmental Management Project – Occupational Medical Dose, ORAULT-TKBS-0017-3, Section 3.2.
• NIOSH concluded it is feasible, using methods available in existing NIOSH procedures, to reconstruct external radiation doses for all FMPC workers for the period from January 1, 1954, through December 31, 1967.

• Although NIOSH now finds that it is not possible to completely reconstruct internal radiation doses for the period from January 1, 1954, through December 31, 1967, NIOSH intends to use any internal monitoring data that may become available for an individual claim (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures). Dose reconstructions for individuals employed at FMPC during the period from January 1, 1954, through December 31, 1967, but who do not qualify for inclusion in the SEC, may be performed using these data as appropriate.

• The NIOSH Director concurred with the Board and recommended the proposed class for addition to the SEC.

Health Endangerment

The Secretary established the health endangerment determination for the class of employees covered by this report based upon the findings summarized below.

(1) Pursuant to 42 C.F.R. § 83.13(c)(3), NIOSH established that there is a reasonable likelihood that such radiation doses may have endangered the health of members of the class. Pursuant to 42 C.F.R. § 83.13(c)(3)(ii), NIOSH specified a minimum duration of employment to satisfy this health endangerment criterion as “having been employed for a number of work days aggregating at least 250 work days within the parameters established for this class or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more other classes of employees in the Cohort.”

(2) NIOSH did not identify any evidence from the petitioners or from other resources that would establish that the class was exposed to radiation during a discrete incident likely to have involved exceptionally high-level exposures, such as a nuclear criticality incident, as defined under 42 C.F.R. § 83.13(c)(3)(i).

(3) The Board concurred with NIOSH’s finding that the health of the class may have been endangered and defined the class according to the 250 work day requirement specified under 42 C.F.R. § 83.13(c)(3)(ii).

V. Effect and Effective Date of Designation

VI. Administrative Review of Designation

The health endangerment determination of the designation provided in this report may be subject to an administrative review within HHS, pursuant to 42 C.F.R. § 83.18(a). On the basis of such a review, if the Secretary decides to expand the class of employees covered by this designation, the Secretary would transmit a supplementary report to Congress providing the expanded employee class definition and the criteria and findings on which the decision was based.