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SEC 12



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MAR 29 2006

Dear Ms.

This is in response to your letter contesting part of the designation of a certain class of employees from the Mallinckrodt Chemical Works facility in St. Louis, Missouri, to be added to the Special Exposure Cohort established under provisions of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

Specifically, this designation was as follows:

Employees of the Department of Energy (DOE) or DOE contractors or subcontractors employed by Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility, during the period from 1942 through 1948, and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

As you know, the regulations implementing EEOICPA provide that a panel of three employees of this Department, independent of the National Institute for Occupational Safety and Health (NIOSH), will conduct an administrative review when such a designation is contested. Such a panel was established, and a copy of its report to me is enclosed. In deciding whether to revise my decision, I considered this report, as well as the information and recommendations provided to me by the NIOSH Director and by the Advisory Board on Radiation and Worker Health, prior to the administrative review. After careful consideration of these documents, I have decided not to revise my April 11, 2005, designation.

Thank you for your efforts in this important area.

Sincerely,

Michael O. Leavitt

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

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JAN 20 2006

The Honorable Michael O. Leavitt  
Secretary of Health and Human Services  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Re: Special Exposure Cohort Administrative Review Panel

Dear Mr. Secretary:

On April 11, 2005, as authorized under the Energy Employees Occupational Illness Compensation Act of 2000 (EEOICPA), 42 U.S.C. § 7384g(b), you designated the following class of employees as an addition to the Special Exposure Cohort (SEC):

Employees of the Department of Energy (DOE) or DOE contractors or subcontractors employed by Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility during the period from 1942 through 1948 and who were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

On May 17, 2005, a Mallinckrodt SEC petitioner, ("the petitioner"), filed a challenge to that decision, contesting the health endangerment determination under EEOICPA implementing regulations at 42 CFR § 83.13(c)(3)(ii) – this section sets out a 250 work day minimum duration of employment to satisfy the health endangerment criterion. The petitioner argued that instead 42-CFR § 83.13(c)(3)(i) should apply – this section states as follows:

For classes of employees that may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures, such as nuclear criticality incidents or other events involving similarly high levels of exposures resulting from the failure of radiation protection controls, NIOSH will assume for the purposes of this section that any duration of unprotected exposure could cause a specified cancer, and hence may have endangered the health of members of the class. Presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, will satisfy the health endangerment criterion.

The petitioner's May 17, 2005, letter states that:

The proposed decision of the 250 day requirement for this group of workers relies upon or is based upon a record of factual error. The episodic releases or short discrete incidences were not taken into account and therefore discriminates against certain employees or classes of employees who may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures.

EEOICPA implementing regulations at 42 CFR § 83.16(b) provide that a petitioner may contest a health endangerment determination by including evidence that the proposed decision relies on a record of either substantial factual errors or substantial errors in the implementation of the regulatory procedures set out in 42 CFR Part 83. We note that the petitioner's challenge is to the factual basis of the proposed decision; the challenge does not allege any error in HHS' implementation of regulatory procedures.

Because of that challenge and pursuant to 42 CFR § 83.16(c), you appointed a panel of three HHS personnel, independent of NIOSH, to conduct an administrative review and provide recommendations concerning the merits of the challenge and the resolution of the issues contested by the challenge. The undersigned, W. Howard Cyr, Ph.D., C. Norman Coleman, M.D., and Kiyohiko Mabuchi, M.D., Dr.P.H., comprise that panel. Pursuant to 42 CFR § 83.16(c), we examined the views and information submitted by the petitioner in the challenge, the proposed decision, the NIOSH evaluation reports, the report containing the recommendations of the Advisory Board on Radiation and Worker Health issued prior to the proposed decision, the information presented to the Advisory Board, and the deliberations of the Board prior to the issuance of its recommendation. We were charged with considering whether or not the proposed decision was supported by accurate factual information, and the principal findings and recommendations of NIOSH and the Advisory Board. Since the petitioner did not raise any errors in regulatory procedures in the challenge, we conclude that we are only addressing the merits of the factual basis of the decision, *i.e.*, whether the Mallinckrodt employees were exposed to exceptionally high levels of radiation during a discrete incident, such as a nuclear criticality event.

Since 42 CFR § 83.16(b) prohibits petitioners from introducing any new information or documentation, our review was based entirely on the administrative record in this case, as described above. A list of the specific documents we reviewed is included at the end of this letter. In particular, we paid special attention to the following documents: (1) the April 11, 2005, report in which you set our your proposed decision ("HHS Designation of Additional Members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act: Designating a Class of Employees from Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility, St. Louis, Missouri"); (2) a memorandum that was a cover letter from Merrill Eisenbud to W.E. Kelley, dated January 31, 1951, re: Report on Mallinckrodt Employees (Attachment A14 of the Mallinckrodt petition), with the attached report, dated November 20, 1950, entitled "An Estimate of Cumulative Multiple Exposures to Radioactive Materials: Mallinckrodt Chemical Works - Plants 4 and 6 - July 1942 to October 1949," written by Hanson Blatz and Merrill Eisenbud (Attachment A15 of the Mallinckrodt petition - we note that the attachment included only pages 1-11 of the report, which do not contain the report's Conclusions); (3) the Mallinckrodt Site Profile (ORAU Team Dose Reconstruction Project for NIOSH, Document Number ORAUT-TKBS-0005, dated March 10, 2005); and (4) the transcript of the open meeting of the Advisory Board, held on February 8 and 9, 2005, at which both NIOSH and the petitioners made presentations.

With respect to your April 11, 2005, proposed decision, your findings regarding health endangerment are set out in section IV., "Health Endangerment," paragraphs (2) and (3). Having determined that it is not feasible to estimate with sufficient accuracy the radiation dose that the class received because of lack of sufficient information, you conclude that there is sufficient evidence to determine that there is a reasonable likelihood that such radiation dose may have endangered the health of the members of the class. In particular, in paragraph (2), you state that "NIOSH found members of the class received episodic exposures to radionuclide dusts and radon gas that could have cumulatively resulted in chronic, potentially substantial exposures to radiation." Therefore, you propose that a class of Mallinckrodt employees who meet the 250 work day criterion set out in 42 CFR § 83.13(c)(3)(ii) be added to the Special Exposure Cohort. Although not stated directly in your proposed decision, we believe this conclusion is consistent with the November 20, 1950, Blatz and Eisenbud report regarding employees with high inhalation doses, as well as with the statement in the January 31, 1951, memorandum that was the cover letter to that report, which says "The report shows that there are 17 employees whose lungs have had more than 1000 rem of exposure." In addition, the Mallinckrodt Site Profile (ORAUT-TKBS-0005) indicates that there were especially high inhalation doses with exposures that were as much as 100 - 200 times the maximum allowable concentration of 50 micrograms per cubic meter (see section 5.3.2). Section 7.3.3 of the Site Profile assumes that workers exposed in the time period of 1942 to 1945 received doses that were comparable to those of later workers with the same jobs.

We think it is particularly important that, while you note that members of the class received episodic, chronic, and potentially substantial exposures to radiation, as described in the paragraph above, you then conclude that there is no evidence to indicate that any of these episodic events was significant enough to be similar to a criticality incident. In paragraph (3), you state that "NIOSH did not identify any evidence from the petitioners or other resources that would establish that the class was exposed to radiation during a discrete incident, such as a nuclear criticality incident, as defined under 42 CFR § 83.13(c)(3)(i)." Both the NIOSH SEC Petition Evaluation Report (SEC 0012-2) and the November 20, 1950, Blatz and Eisenbud report, contain descriptions of possible exposures to and internal doses from several different types of isotopes, but contain no data on any discrete incidents in which employees were exposed to very high doses of radiation, similar to that of a criticality event. In addition, as stated in the previous paragraph, the Mallinckrodt Site Profile (ORAUT-TKBS-0005) referred to possible elevated doses in the class members, but did not describe any events that could be considered to be equivalent to a criticality event. Finally, the petitioners did not present any evidence of any such discrete criticality-type events either in the petition and accompanying materials, in the letter challenging your proposed decision, or in the open meeting of the Advisory Board, held on February 8 and 9, 2005.

Based on our analysis of the record, we conclude that an extensive investigation was conducted pursuant to the EEO/CPA statute and implementing regulations, and that your decision contained no evidence of factual error, was supported by accurate information from both written and verbal testimony, and was factually correct. Accordingly, we believe that the challenge to your proposed decision is without merit.

The Honorable Michael O. Leavitt - Page 4

Sincerely,



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W. Howard Cyr, Ph.D.  
Leader, Radiation Biology Laboratory  
Office of Science and Engineering Laboratories  
Center for Devices and Radiological Health  
Food and Drug Administration



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C. Norman Coleman, M.D.  
Head, Experimental Therapeutics Section  
Senior Principal Investigator  
Radiation Oncology Branch  
Clinical Center  
National Institutes of Health



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Kiyotiko Mabuchi, M.D., Dr.P.H.  
Division of Cancer Epidemiology and Genetics  
National Cancer Institute  
National Institutes of Health

cc. John O. Agwunobi, M.D., M.P.H., M.B.A.  
Assistant Secretary for Health  
Department of Health and Human Services

Documents Reviewed by the Special Exposure Cohort Administrative Review Panel:

1. Special Exposure Cohort Petition Submitted on behalf of the Mallinckrodt Employees, dated 7/17/04, and supporting attached documents A1-A18 (with fax cover sheet from to Larry Elliot, transmitting Special Exposure Cohort Petition under the Energy Employees Occupational Illness Compensation Act, dated 7/15/04)
2. Supplements to Mallinckrodt Petition, dated 7/21/04, 9/30/04 (with fax cover sheet from to Dave Sunin, dated 9/30/04), 10/13/04, and 10/22/04
3. Identical letters, dated December 8, 2004, to Robert W. Presley, Wanda I. Munn, Richard L. Espinosa, James M. Melius, Antonio Andrade, Charles Leon Owens, Genevieve S. Roessler, Henry A. Anderson, Mark A. Griffon, Michael H. Gibson, and Roy DeHart, from Larry J. Elliott, Director, Office of Compensation Analysis and Support, NIOSH, with the following three enclosures: (1) Petition Evaluation Plan SEC00012, dated 12/8/04; (2) Summary of SEC Petition 00012, dated 12/8/04; and (3) Mallinckrodt Special Exposure Cohort Petition, dated 7/17/04
4. NIOSH SEC Evaluation Reports for Mallinckrodt Petition SEC-00012-1 (dated 2-1-05) and SEC-00012-2 (dated 2-2-05)
5. Supplement to NIOSH SEC Evaluation Reports for Mallinckrodt Petition (SEC-00012-1 and 2): Discussion of Issues Identified During the Advisory Board Deliberation of the Mallinckrodt Evaluation Reports on 2/08-2/09/05 in St. Louis, dated 3/30/05
6. Letter, dated March 11, 2005, from Larry J. Elliott, Director, Office of Compensation Analysis and Support, NIOSH, to Paul L. Ziemer, with enclosed Mallinckrodt Site Profile – “ORAU Team, Dose Reconstruction Project for NIOSH - Basis for Development of an Exposure Matrix for the Mallinckrodt Chemical Company St. Louis Downtown Site and the St. Louis Airport Site, St. Louis, Missouri, Period of Operation: 1942-1958,” Document Number: ORAUT-TKBS-0005, dated 3/10/05
7. Letter, dated March 11, 2005, from Dr. Paul L. Ziemer, Chairman, Advisory Board on Radiation and Worker Health (ABRWH), to Michael O. Leavitt, Secretary of HHS
8. Letter, undated, from John Howard, Director, NIOSH, to the Secretary, HHS, Re: Designating Employees of Mallinckrodt Chemical Company as Members of the Special Exposure Cohort (“the SEC”) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (“EEOICPA”): Action Required by April 11, 2005
9. Letter, dated April 11, 2005, from Michael O. Leavitt, Secretary of HHS, to the Honorable J. Dennis Hastert, Speaker of the House of Representatives, with enclosed “HHS Designation of Additional Members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act: Designating a Class

of Employees from Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility, St. Louis, Missouri”

10. Identical letters, dated February 2, 2005, to Paul Ziemer, Robert W. Presley, Wanda Munn, Richard Espinosa, James Melius, Antonio Andrade, Charles Leon Owens, Genevieve S. Roessler, Henry Anderson, Mark A. Griffon, Michael Gibson, and Roy DeHart, from Larry J. Elliott, Director, Office of Compensation Analysis and Support, NIOSH
11. Transcript of the Meeting of the Advisory Board on Radiation and Worker Health, held at the Adam's Mark, St. Louis, Missouri, on February 8 and 9, 2005 (excerpt concerning the Mallinckrodt SEC Petition)
12. Powerpoint Presentation, dated February 8, 2005, by Larry Elliot, re: Mallinckrodt SEC Petition Evaluation Report
13. Identical letters dated February 17, 2005, from Larry J. Elliott, Director, Office of Compensation Analysis and Support, NIOSH, to \_\_\_\_\_ and \_\_\_\_\_ with enclosed “Notes and Summary of Visit by M.E. Mason - August 1975,” dated 9/2/1975
14. Letter dated May 17, 2005, from \_\_\_\_\_ to Michael Leavitt, Secretary of HHS (with fax cover sheet transmitting letter, dated 5/17/05)
15. Executive Order 13179, “Providing Compensation to America’s Nuclear Weapons Workers,” dated December 7, 2000
16. *Federal Register* Final Rule, dated May 28, 2004, “Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000,” 42 C.F.R. Part 83

May 17, 2005

U.S. Department of Health and Human Services  
200 Independence Ave., SW.  
Washington, DC  
20201

05-17-05P04:53 RCVD

Att : Honorable Secretary Michael Levitt  
Secretary of Health and Human Services

Re: Mallinckrodt SEC

Dear Sir:

I would like to respectfully contest and appeal the decision regarding the 250 day requirement under section 83.16 B of the EEOICPA, health endangerment issue. The proposed decision of the 250 day requirement for this group of workers relies upon or is based upon a record of factual error

The episodic releases or short discrete incidences were not taken into account and therefore discriminates against certain employees or classes of employees who may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures.

This section states that presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, will satisfy the health endangerment criterion.

I hope that you will be able to advise me in this matter.

Sincerely,

cc: Mr. John Howard            NIOSH  
    Mr. Larry Elliot         NIOSH