

used to falsely represent Respondent's own experiment for bone nodules formed in osteoblastic niche cells from young and aged mice.

- Respondent falsely represented eight (8) flow cytometry contour plots as different experimental results by using identical plots but with different labels and different numerical percentages. Specifically, the following contour plots in the *Blood* paper, the *Nature* paper, an earlier version of the *Nature* paper submitted to *Science* (hereafter referred to as the "*Science* manuscript"), and a July 2008 PowerPoint presentation were identical but were labeled differently:
  - a. Panels 4 and 2 in Figure 6C, *Blood* paper, and panels 1 and 2, respectively, in supplementary Figure 3b, *Nature* paper
  - b. Panel 3 in Figure 6C, *Blood* paper, and panel 1 in Figure 2, July 2008 PowerPoint presentation
  - c. Panels 1 and 2, Figure 2b, *Science* manuscript, and panels 2 and 3, respectively, in Figure 2, July 2008 PowerPoint presentation
  - d. Panels 2, 3, and 4, supplemental Figure 4A, *Blood* paper, and panels 3, 1, and 2, respectively, in Figure 4B, *Science* manuscript

Both the Respondent and HHS want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. Respondent neither admits nor denies ORI's finding of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent. Dr. Mayack has voluntarily agreed:

(1) If within three (3) years from the effective date of the Agreement, Respondent does receive or apply for U.S. Public Health Service (PHS) support, Respondent agrees to have her research supervised for a period of three (3) years beginning on the date of her employment in a research position in which she receives or applies for PHS support and to notify her employer(s)/ institution(s) of the terms of this supervision; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported

research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) If within three (3) years from the effective date of the Agreement, Respondent does receive or apply for PHS support, Respondent agrees that any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) To exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on July 27, 2012.

**FOR FURTHER INFORMATION CONTACT:**

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

**John Dahlberg,**

*Director, Division of Investigative Oversight, Office of Research Integrity.*

[FR Doc. 2012-21236 Filed 8-27-12; 8:45 am]

**BILLING CODE 4150-31-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10003]

**Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB); Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Correction of notice.

**SUMMARY:** This document corrects a technical error in the notice [Document Identifier: CMS-10003] entitled "Notice of Denial of Medical Coverage (or Payment)" that was published in the July 6, 2012 (77 FR 40064) **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:**

William Parham, (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the FR Doc. 2012-16514 of July 6, 2012 (77 FR 40064), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled "Notice of Denial of Medical Coverage (or Payment)."

In the July 6, 2012 notice, we listed the incorrect contact information. Therefore, we are correcting that error in this notice.

**II. Correction of Error**

In FR Doc. 2012-16514 of July 6, 2012 (77 FR 40064), make the following correction:

On page 40068, first column, fourth full paragraph, on the fifteenth line in the paragraph beginning with "(For policy questions regarding, " and ending with, "410-786-0273)," is corrected to read as follows.

"(For policy questions regarding this collection contact Kathryn McCann Smith at 410-786-7623.)"

Dated: August 22, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2012-21076 Filed 8-23-12; 11:15 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-E-0102]

**Determination of Regulatory Review Period for Purposes of Patent Extension; TORISEL**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for TORISEL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product TORISEL (temsirrolimus). TORISEL is indicated for the treatment of advanced renal cell carcinoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TORISEL (U.S. Patent No. 5,362,718) from Wyeth, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated August 7, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TORISEL represented the first permitted

commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for TORISEL is 3,290 days. Of this time, 3,052 days occurred during the testing phase of the regulatory review period, while 238 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 29, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 5, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for TORISEL (NDA 22-088) was submitted on October 5, 2006.

3. *The date the application was approved:* May 30, 2007. FDA has verified the applicant's claim that NDA 22-088 was approved on May 30, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,764 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by October 29, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 25, 2013. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with

the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 12, 2012.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2012-21239 Filed 8-27-12; 8:45 am]

**BILLING CODE 4160-01-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0253]

#### Privacy Act of 1974; Report of a New System of Records; FDA Records Related to Research Misconduct Proceedings

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of a Privacy Act system of records.

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**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974 (the Privacy Act) and the Food and Drug Administration's (FDA's) regulations for the protection of privacy, FDA is publishing notice of a new Privacy Act system of records entitled "FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC" System No. 09-10-0020. Under the Department of Health and Human Services' (HHS' or the Department's) Public Health Service Policies on Research Misconduct, FDA has responsibilities for addressing research integrity and misconduct issues related to FDA supported activities. This system contains records related to the processing and reviewing of allegations of scientific research misconduct levied against an individual (the respondent) who is an agent of, or affiliated by contract or agreement with, FDA, or an FDA employee involved in intramural research. Research misconduct proceedings include allegation assessments, inquiries, investigations, oversight reviews by HHS' Office of Research Integrity (ORI), hearings, and administrative appeals.

**DATES:** Effective Date: The new system of records will be effective on August 28, 2012, with the exception of the routine uses and the requested exemptions. The routine uses will become effective on October 12, 2012. As detailed in the companion