Dated: *May 28, 2010.*

Martique Jones,

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

[FR Doc. 2010–13302 Filed 6–3–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10203]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Health Outcomes Survey (HOS); *Use:* CMS has a responsibility to its Medicare beneficiaries to require that care provided by managed care organizations under contract to CMS is of high quality. One way of ensuring high quality care in Medicare Managed Care Organizations (MCOs), or more commonly referred to as Medicare Advantage Organizations (MAOs), is through the development of standardized, uniform performance measures to enable CMS to gather the data needed to evaluate the care provided to Medicare beneficiaries.

The goal of the Medicare HOS program is to gather valid, reliable, clinically meaningful health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and improving health. All managed care plans with Medicare Advantage (MA) contracts must participate. CMS, in collaboration with the National Committee for Quality Assurance (NCQA), launched the Medicare HOS as part of the Effectiveness of Care component of the former Health Plan Employer Data and Information Set, now known as the Healthcare Effectiveness Data and Information Set (HEDIS®).

The HOS measure was developed under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. The measure includes the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techinques. In addition to health outcomes measures, the HOS is used to collect the Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management, and Osteoporosis Testing in Older Women HEDIS® measures. The collection of Medicare HOS is necessary to hold Medicare managed care contractors accountable for the quality of care they are delivering. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicar Advantage program. *Form Number:* CMS–10203 (OMB#: 0938–0701; *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 1,099,560 *Total Annual Responses:* 1,099,560; *Total Annual Hours:* 366,520 (For policy questions regarding this collection contact Chris Haffer at 410–786–8764. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *August 3, 2010:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Date: *May 28, 2010.*

Martique Jones,

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

[FR Doc. 2010–13303 Filed 6–3–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0278]

Determination That Cysteine Hydrochloride Injection, USP, 7.25%, Was 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) is announcing its determination that Cysteine Hydrochloride Injection, USP, 7.25% (Cysteine HCl), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Cysteine HCl if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved.

Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Cysteine HCl is the subject of NDA 19–523, most recently held by Hospira, Inc. (Hospira), and initially approved on October 22, 1986. Cysteine HCl is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis. Hospira notified FDA in a letter dated May 26, 2005, that it had not commercially manufactured and marketed Cysteine HCl, and voluntarily asked that the NDA be withdrawn. The drug product was moved to the "Discontinued Drug Product List" section of the Orange Book, and FDA withdrew approval of NDA 19–523 effective June 16, 2006 (71 FR 34940). In previous instances (see, e.g., 74 FR 63404, December 3, 2009; 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. Regulus Pharmaceutical Consulting, Inc., submitted a citizen petition, dated April 30, 2008 (Docket No. FDA–2008–P–0278), under 21 CFR 10.30, requesting that the agency determine whether Cysteine HCl was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that Cysteine Hydrochloride Injection, USP, 7.25%, was not withdrawn for reasons of safety or effectiveness. We have also independently evaluated relevant literature and have found no information that would indicate that this product was withheld from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Cysteine Hydrochloride Injection, USP, 7.25%, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Cysteine Hydrochloride Injection, USP, 7.25% may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that the labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13463 Filed 6–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the United States in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

888-mel: A Target for Anti-Tumor Immune Responses

Description of Invention: Scientists at the National Institutes of Health (NIH) have developed a human melanoma cell line designated 888-mel from the resected tumor of a 26-year old Caucasian female (patient 888) diagnosed with metastatic melanoma, a frequently terminal cancer. The 888-mel cell line was derived from three separate subcutaneous melanoma lesions on the patient and possesses many characteristics representative of melanoma cell lines developed by these researchers. Most prominently, the 888-mel cell line was used to develop a tumor infiltrating lymphocyte (TIL) culture with high affinity for the tumor cells of patient 888. When the TIL 888 culture was provided as an autologous adoptive immunotherapy treatment to patient 888 in combination with interleukin-2 (IL–2), a complete remission of subcutaneous, lung, and mucosal metastases was observed in the patient for over three years.

Since this medical breakthrough, the 888-mel cell line has been well characterized through various laboratory procedures and data involving this cell line has been published as part of numerous articles. Studies have shown that the cell line expresses a variety of tumor associated antigens (TAAs), including tyrosinase, TRP1, TRP2, gp100, MART–1, p15, gp75, mutated beta-catenin, and p53. However, 888-mel does not normally express the MAGE 1, 2, or 3 TAAs. Many melanoma cell lines are HLA–A2 restricted, but the 888-mel cell line is HLA–A2 negative. The HLA class I typing for this cell line is as follows: HLA–A0101, A2402, B55, B62, Cw5201, Cw55, DRbl*1502, DRbl*1610, DQbl*0601, DRb5*0102, DRb5*0203. 888-mel is a validated source of HLA class I peptides utilized in screens that test the reactivity of TIL cultures that are candidates for adoptive immunotherapy trials. 888-mel is also a standard cell line for studying immune responses in cancer, particularly T cell responses. Other experiments show that roscovitine, a cyclin-dependent kinase inhibitor, can induce apoptosis in the 888-mel cell line, so these cells may be useful in various cell death studies.