

production of a sterile preoperative skin prep product?

5. How would the market change if all patient preoperative skin preparations were required to be manufactured sterile?

6. What can FDA do to help manufacturers overcome challenges in this area?

B. Extrinsic Contamination

1. Products manufactured sterile can be contaminated as soon as they are opened for the first time. What steps can be taken to reduce the risk of extrinsic contamination of patient preoperative skin preparations?

2. Excluding the use of these products before surgical procedures or injections, are these products used for other purposes in healthcare or home settings (e.g., wound care or maintenance care for indwelling catheters)? If so, what is the extent of these uses in healthcare or home settings? What settings or uses comprise the majority of utilization for single-use products? What settings or uses comprise the majority of utilization for multiple-use products?

3. To what extent are multiple-use containers of patient preoperative skin preparations further processed (e.g., diluted, mixed, or repackaged for subsequent redistribution) in healthcare or home settings? If these products are diluted, mixed, or repackaged, are they handled aseptically? Why are these products diluted?

4. Should patient preoperative skin preparations be marketed only in single-use containers? If single and multiple-use containers are permitted, in which ways could single-use containers be clearly distinguished from multiple-use containers (e.g., by labeling, size, volume, presence/absence of applicator)? What technical and practical challenges would manufacturers and users face should there be regulatory requirements that limit package sizes for multiple-use patient preoperative skin preparations?

5. Can product labeling, for example, instructions to "discard X days after opening," be used to reduce the risk of adverse events associated with extrinsic contamination of patient preoperative skin preparations? How could a "discard by" date be established for individual products and how meaningful would such a date be in the context of current practices?

6. Are healthcare facilities or other entities providing information or training on safe use of multiple-use patient preoperative skin preparations, or taking other steps to reduce the risk of extrinsic contamination of these multiple-use products? If so, please

describe these efforts and any available information on their effectiveness.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by management and technical personnel from the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C and § 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts* for more details). To the extent that the conditions for the hearing as described in this notice conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. References

The following references have been placed on display in the Division of Dockets Management (see *Comments*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Weber, D.J., W.A. Rutala, and E.E. Sickbert-Bennett, "Outbreaks Associated with Contaminated Antiseptics and Disinfectants," *Antimicrobial Agents and Chemotherapy*, 51:4217–4224, 2007.

2. *The United States Pharmacopeia 35-National Formulary 30*. The United States Pharmacopeial Convention, Inc., MD, "Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use," Chapter 1111:691, 2012.

3. Pharmaceutical Science and Clinical Pharmacology Advisory Committee meeting transcript, available at: <http://www.fda.gov/downloads/AdvisoryCommittee/Committees/MeetingMaterials/Drugs/AdvisoryCommittee/forPharmaceuticalScienceandClinicalPharmacology/UCM179891.pdf>, 2009.

Dated: November 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

60-Day Proposed Information Collection; Request for Public Comment: Indian Health Service Contract Health Services Report

AGENCY: Indian Health Service.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–0002, "IHS Contract Health Service Report." *Type of Information Collection Request:* Extension, without change, of a currently approved information collection, 0917–0002, "IHS Contract Health Service Report." *Form Number:* IHS 843–1A. The form can be found on the Public Use Forms Web page(s) at the IHS Web site (<http://www.ihs.gov/cio/puf/>) and the Department of Health and Human Services' Web site (<http://www.hhs.gov/forms/publicuse.html>).

Need and Use of Information Collection: The IHS Contract Health Service (CHS) Program, located in the Office of Resource Access and Partnerships, needs this information to certify that the health care services requested and authorized by the IHS have been performed by the CHS provider(s) to have providers validate services provided; to process payments for health care services performed by such providers; and to serve as a legal document for health and medical care authorized by IHS and rendered by health care providers under contract with the IHS. *Affected Public:* Patients, health and medical care providers or Tribal Governments. *Type of Respondents:* Health and medical care providers.

Burden Hours: The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Average burden hour per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden hours
IHS 843-1A	7,977	52	3/60	20,740
Total				20,740

*For ease of understanding, burden hours are also provided in actual minutes.

The total estimated burden for this collection is 20,740 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information: Send your written comments and requests for more information on the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Tamara Clay, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852; call non-toll free (301) 443-1611; send via facsimile to (301) 443-2316, or send your email requests, comments, and return address to tamara.clay@ihs.gov.

Comment Due Date: Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: November 9, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2012-28236 Filed 11-20-12; 8:45 am]

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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 U.S. 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.

FOR FURTHER INFORMATION CONTACT: 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.

A New Class, Now in Session: the First HLA Class II Restricted T Cell Receptor That Recognizes the Cancer Testis Antigen, MAGE-A3, Developed for Cancer Immunotherapy

Description of Technology: NIH scientists have developed T cell receptors (TCRs) against the melanoma antigen family A3 (MAGE-A3) tumor antigen in the context of major histocompatibility complex (MHC) class II molecule HLA-DP-beta1*04. They are the first HLA class II restricted MAGE-A3 TCRs developed for use in adoptive immunotherapy. Previously developed MAGE-A3 TCRs are HLA class I restricted and generate CD8+ T cell responses to mediate tumor regression in some patients with MAGE-A3+ tumors. Other patients may not respond due to a lack of CD4+ T cells participation. Cancer immunotherapy

with these new HLA class II TCRs could yield a robust and effective CD4+ T cell immune response that selectively targets MAGE-A3 expressing tumors without generating toxicity against healthy cells.

MAGE-A3 is a cancer testis antigen expressed on many types of cancer cells that blocks the functions of tumor suppressor proteins to mediate tumor growth and spreading. MAGE-A3 is not expressed on normal cells other than non-MHC expressing germ cells of the testis, which do not generate an immune response. Thus, MAGE-A3 represents an ideal target for cancer immunotherapies that are predicted to generate fewer toxic side effects than current standard cancer treatments.

Potential Commercial Applications:

- A personalized immunotherapy to mediate regression of many types of cancers using human T cells expressing a HLA class II TCR.
- An adoptive immunotherapy combining T cells engineered to express a HLA class I restricted TCR with HLA class II TCR-expressing T cells to enhance the antitumor response by eliciting CD8+ and CD4+ T cell immune responses in patients.
- A research tool to investigate signaling pathways in MAGE-A3 antigen-expressing cancer cells.
- An in vitro diagnostic tool to screen for cells expressing the MAGE-A3 tumor antigen.

Competitive Advantages:

- Class I restricted TCRs can only treat a subset of patients, but since ~80% of patients express the HLA-DP-beta1*04 class II HLA allele, this TCR expands the population pool treatable with MAGE-A3 TCRs to include the majority of patients.
 - MAGE-A3 is a highly expressed tumor target on many cancer cells, so MAGE-A3 TCR therapy should be a viable treatment option for many cancer cases.
 - MAGE-A3 is only expressed on tumor cells and non-MHC expressing cells so these TCRs should target MAGE-A3 expressing tumor cells with little or no side effects/toxicity to normal cells.
- Development Stage:*
- Early-stage.
 - Pre-clinical.
 - In vitro data available.