

guidance document entitled "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 30, 1999 (64 FR 41744), FDA announced the availability of a draft guidance for comment entitled "Medical Glove Guidance Manual." (See <http://www.fda.gov/cdrh/dsma/135.html> for the draft guidance.) Elsewhere in the same issue of the **Federal Register** (64 FR 41710), FDA proposed that the 1999 draft guidance serve as a special control for class II gloves. However, chapter 4 of the 1999 draft guidance contained a section that discussed PMAs for absorbable powder for lubricating surgeon's gloves. Because the section discussing PMAs for absorbable powder is not relevant to class II gloves, FDA is removing this section and issuing it as a separate guidance document. FDA did not receive any comments on this section of the 1999 draft guidance. Because the recommendations in this section were available in draft form for comment, FDA is issuing this guidance as a final document. As with any guidance, however, you may submit comments at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on PMAs for

absorbable powder for lubricating a surgeon's glove. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381, or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1230) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910-0231). The labeling provisions addressed in the guidance have been approved by OMB under the PRA, OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 2004.

Beverly Cherniak Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04-8306 Filed 4-12-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request Health Information National Trends Survey (HINTS) II

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Health Information National Trends Survey (HINTS) II. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Health Information National Trends Survey (HINTS) is a biennial survey designed to provide nationally representative, population-based data on health information for the United States. The NCI funded HINTS to assist in its effort to (1) encourage programmatic and interdisciplinary approaches to cancer communication research, and (2) accelerate development of innovative health communication models, theories, and research strategies in cancer prevention, control, and care. HINTS II, scheduled to commence in early 2005, will preserve the methodological integrity of the first cycle of HINTS by using the telephone as the primary mode of data collection as well as

retaining approximately 50% of the questionnaire content. In addition, HINTS II will experiment with alternative modes of data collection (i.e., the Internet). Data will be used (1) to understand individuals' sources of and access to cancer-related information; (2) to measure progress in improving cancer knowledge and communication to the general public; (3) to develop appropriate messages for the public

about cancer prevention, detection, diagnosis, treatment, and survivorship; and (4) to identify research gaps and guide decisions about NCI's research efforts in health promotion and health communication. *Frequency of response:* One-time. *Affected public:* Individuals. *Type of Respondents:* U.S. Adults, Pilot Survey, Screeners and Interview. The annual reporting burden is as follows: *Estimated Number of Respondents:*

10,389; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .37; and *Estimated Total Annual Burden Hours Requested:* 3,836. The annualized cost to respondents is estimated at \$38,360. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Frequency of response	Average hours per response	Annual hour burden
Pilot Survey	150	1	.4167	63
HINTS II Screener	10,239	1	.0833	854
HINTS II Interview*	7,004	1	.4167	2,919
Totals				3,836

*HINTS II interview respondents are a subset of the screener respondents (N = 10,389).

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Bradford W. Hesse, Ph.D., Project Officer, National Cancer Institute, NIH, EPN 4068, 6130 Executive Boulevard MSC 7365, Bethesda, Maryland 20892-7365, or call non-toll-free number (301) 594-9904, or FAX your request to (301) 480-2198, or E-mail your request, including your address, to heseb@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of this notice.

Dated: April 1, 2004.

Rachelle Ragland-Greene,

OMB Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 04-8270 Filed 4-12-04; 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, DHHS.

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.

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.

Query Tool for Accurate Protein Identification

Rodney L. Levine (NHLBI)

U.S. Patent Application No. 10/446,865 filed 29 May 2003 (DHHS Reference No. E-306-2002/0-US-01)

Licensing Contact: Michael Shmilovich; 301/435-5019; shmilovm@mail.nih.gov.

PHS seeks a commercial developer for the following software database query tool: A data-mining tool (software based query generator) that provides a script that identifies an isolated protein by using physical properties of the protein and submitting the query into a protein database (e.g., SWISS-PROT). The inventors identified that by combining an accurate determination of the ratio of at least one amino acid per molecule and at least one physical parameter of the protein; an accurate and unique match can be made by the query results. Parameters include the ratios of amino acids to others (e.g., C/F, W/C, C/Y etc.), the molecular weight, the ratio of positively to negatively charged moieties, and/or the isoelectric point.

Bromotyrosine-Derived Inhibitors of Mycothiol-S-Conjugate Amidase

Carole A. Bewley *et al.* (NIDDK)

U.S. Provisional Application No. 60/395,219 filed 10 Jul 2002 (DHHS Reference No. E-196-2002/0-US-01); PCT Application No. PCT/US03/21456 filed 09 Jul 2003, which published as WO 04/004659 on 15 Jan 2004 (DHHS Reference No. E-196-2002/0-PCT-02)

Licensing Contact: Michael Ambrose; 301/594-6565; ambrose@mail.nih.gov.

Mycobacterium tuberculosis has reemerged as a leading cause of death by an infectious agent, especially among populations that are immunocompromised. With this increase in the rate of infection there has also been an increase in the number of drug resistant strains, making treatment of such infections more difficult. As such, the development of new antituberculars with novel modes