

Dated: April 21, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Granting of an Exclusive License

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office of the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is contemplating granting a worldwide exclusive license to AES Raptor, LLC, located in North Kansas City, Missouri. Under this exclusive license, only AES Raptor, LLC would be permitted to commercialize the technology described in the patent applications listed below. CDC intends to grant rights to commercialize this invention to no other licensees. The patent rights in this invention have been assigned to the government of the United States of America. The invention to be licensed is:

Title: Barricade System and Barricade Bracket for Use Therein, CDC Ref. #: I-016-04, a safety rail system that provides protection to individuals working on inclined structures. The system is designed to prevent individuals from falls to a lower level.

U.S. Patent No.: 7,509,702.

U.S. Application No.: 11/257,472.

Filing date: 10/24/2005.

Canadian Application No.: 2,565,354.

Filing date: October 23, 2006.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Requests for a copy of this patent application, inquiries, comments, and other materials relating to the contemplated licenses should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, telephone: (770) 488-8610; facsimile: (770) 488-8615.

Applications for an exclusive license filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Only written comments and/or applications for a license which are received by CDC within thirty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 31, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0614. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-

796-7651,

Juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile; Interim Final Rule—(OMB Control Number 0910-0614)—Extension

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the nation (see PHS Act, section 319F-2, 42 U.S.C. 247d-6b). This collection of medical products for use during national health emergencies, known as the Strategic National Stockpile (SNS), is to “provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.”

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352).

In the **Federal Register** of December 28, 2007 (72 FR 73589), FDA published an interim final rule entitled “Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile.” In the interim final rule, FDA issued regulations under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), which allow the appropriate FDA Center Director to grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the