

ownership, operator, the purpose of the flight and the persons on board the aircraft.

#### FAA Policy

- Public aircraft status is not an “automatic” status granted by the existence of a contract between a civil operator and a government agency.
- The FAA considers ALL contracted operations to be civil aircraft operations, unless:
  - The contracting government entity provides the operator with a written declaration (from the contracting officer or higher-level official) of public aircraft status for designated, qualified flights;
  - The contracted operator notifies the FAA Flight Standards District Office (FSDO) having oversight of the operator (or the operation, as appropriate) that it has contracted with a government entity to conduct “eligible” public aircraft operations;
  - The contracted operator submits the written declaration to the FSDO with jurisdiction having oversight;
  - The flight(s) in question are determined to be legitimate public aircraft operations under the terms of the statute; and
  - The declaration is made in advance of the proposed public aircraft flight.
  - To implement this policy and collect data, the FSDO having oversight of the contracted operator will record receipt of these declarations by electronic means.

Contracted government entities are cautioned that public aircraft operations performed by civil operators create a significant transfer of liability to the contracting government entity, and that FAA oversight ceases.

Civil operators are cautioned that unless there is a declaration of public aircraft status, all operations must be conducted in accordance with all applicable civil aviation regulations, and that the FAA retains oversight and enforcement authority for any deviation from the provisions of Title 14 of the Code of Federal Regulations (14 CFR). Operators are also cautioned that it is their responsibility to refuse a contract to perform operations that violate 14 CFR if they cannot ensure that the government entity offering the contract has declared that operation as a public aircraft operation and that such flight meets the public aircraft eligibility requirements as outlined in the statute.

The FAA is revising Advisory Circular 00.1–1, Government Aircraft Operations, and FAA Order 8900.1, Flight Standards Information Management System. These revisions will more fully address public aircraft policy issues and implementation.

Government entities with experience using civil operators under contract are invited to share their experience and suggestions concerning implementation of this policy. Government entities may submit comments to [PublicAircraft@faa.gov](mailto:PublicAircraft@faa.gov) to be considered as the FAA continues to refine the public aircraft operations policy.

Issued in Washington, DC, on March 17, 2011.

**John W. McGraw,**

*Acting Director, Flight Standards Service.*

[FR Doc. 2011–6894 Filed 3–22–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA–2010–N–0029]

#### Medical Devices; Ovarian Adnexal Mass Assessment Score Test System; Labeling; Black Box Restrictions

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulation classifying ovarian adnexal mass assessment score test systems to restrict these devices so that a prescribed warning statement that addresses a risk identified in the special controls guidance document must be in a black box and must appear in all labeling, advertising, and promotional material. The black box warning mitigates the risk to health associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. Elsewhere in this issue of the **Federal Register**, FDA is announcing a final rule that classifies the ovarian adnexal mass assessment score test system into class II (special controls).

**DATES:** Submit either electronic or written comments by May 23, 2011.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2010–N–0029, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA–2010–N–0029. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993–0002, 301–796–6217.

#### SUPPLEMENTARY INFORMATION:

#### I. What is the background of this proposed rule?

##### A. Ovarian Adnexal Mass Assessment Score Test System

An ovarian adnexal mass assessment score test system measures one or more analytes in serum and combines the values into a single score that is then used to determine the likelihood that the pre-surgical adnexal mass in a woman not yet referred to an oncologist, is malignant. An ovarian adnexal mass assessment score test system is intended for use in those patients for whom surgery is planned, and should not be used to decide whether or not a patient should receive surgery. The test is used in conjunction with a clinical and radiological evaluation of the patient by physicians in determining whether the patient should be referred to a gynecologic oncologist for surgery.

##### B. Identified Risk to Health

The ovarian adnexal mass assessment score test system is not indicated for use as a screening or diagnostic test for ovarian cancer. Off-label use of the test (*e.g.*, in patients who are not already

identified as needing surgery for pelvic mass or without reference to an independent clinical/radiological evaluation of the patient), may lead to a high frequency of unnecessary further testing and surgery due to false positive results, or to delay in tumor diagnosis due to false negative results.

## **II. Why is FDA proposing to require black box warnings on ovarian adnexal mass assessment score test system labeling, advertising, and promotional material?**

FDA has determined that in order to provide reasonable assurance of safety and effectiveness, it is necessary to restrict the ovarian adnexal mass assessment score test system to sale, distribution, and use with labeling, advertising, and promotional material that bears a warning statement in a

black box that alerts users to the risk associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. While FDA is establishing as a special control “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System” which recommends a black box warning to address the risk of off-label use, FDA believes it is necessary to require this warning in labeling and advertising by restricting the device under section 520(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(e)). A notice of availability of this special controls guidance document is published elsewhere in this issue of the **Federal Register**.

In cases in which class II and class III devices have significant risks that would make the devices unsafe if used inappropriately, FDA believes the risks need to be explained in warning statements placed in a black box that is displayed prominently in the labeling, advertising, and promotional material to ensure awareness by the end user. Awareness of these important risks by the end user enables these devices to be used safely. In this case, a prominent black box warning, which alerts the user to the limitations of this device, is necessary in all labeling, advertising, and promotional materials to allow ovarian adnexal mass assessment score test system devices to be used safely. The proposed prominent black box warning would read as follows:

PRECAUTION: The [test name] should not be used without an independent clinical/radiological evaluation and is **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the [test name] carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

## **III. What is the legal authority for this proposed rule?**

FDA is issuing this proposed rule under the authority of section 520(e) of the FD&C Act, which authorizes FDA to restrict sale, distribution, and use of devices upon certain conditions. FDA is also issuing this proposed rule under general device and administrative provisions of the FD&C Act (sections 501, 510, 513, 515, 520, and 701 (21 U.S.C. 351, 360, 360c, 360e, 360j, and 371, respectively)).

## **IV. What is the environmental impact of this proposed rule?**

FDA has determined under 21 CFR 25.34(b) and (f) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## **V. What is the economic impact of this proposed rule?**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act

(5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would strengthen existing cautions against misuse of a new product, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and

benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

An ovarian adnexal mass assessment test system is a device that measures one or more proteins in serum to yield a single result for the likelihood that an adnexal pelvic mass in a woman is malignant. Such a test would identify women whose planned gynecologic surgery would benefit from referral to a gynecological oncologist, despite negative results from other clinical and radiographic tests for ovarian cancer.

In considering the appropriate level of regulatory oversight for this device, FDA concluded in classifying the device that general and special controls to minimize the risk of false positive and false

negative results, and risks associated with improper off-label use would provide a reasonable assurance of safety and effectiveness of the ovarian adnexal mass assessment test system. The special controls guidance recommends use of a black box warning to minimize these risks. Without such a strong warning, ovarian adnexal mass assessment test systems might be used as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. Off-label use of the test or the use of test results without consideration of other diagnostic testing and clinical assessment could pose a risk for morbidity and mortality due to nonreferral for oncologic evaluation and treatment.

In order to require the specific black box warning on labeling and on all advertising and promotional materials for the device, FDA is issuing this proposed rule under section 520(e) of the FD&C Act. Through this action, the Agency proposes to require a black box warning on product labeling, advertising, and promotional materials for ovarian adnexal mass assessment test systems. This warning would make users aware of the limitations of this device and the serious risks associated with its misuse. With the proposed addition of this black box warning to product labeling, advertising, and marketing materials, the Agency concludes there would be a reasonable assurance of the safety and effectiveness of ovarian adnexal mass assessment test systems.

The economic impact of this proposed rule is expected to be very small. We are aware of a single manufacturer producing a single product that would be affected by this black box warning. The manufacturer should be able to incorporate the warning in the course of developing its product labeling. The admonition against off-label use for this device already exists, so the addition of this type of warning is not expected to have a significant effect on the market for this product. The expected impact of this proposal on the market for this product would be a reduction in off-label use among the small number of

users who would be undeterred by a less visible warning.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposal would impose almost no cost on manufacturers. The proposed black box warning would strengthen an existing admonition against off-label use and would not significantly affect usage. Impacts on any entities would be so small as to be difficult to quantify. For these reasons, the Agency proposes to certify that this rule would not have a significant economic impact on a substantial number of small entities.

#### **VI. How does the Paperwork Reduction Act of 1995 apply to this proposed rule?**

FDA concludes that labeling provisions of this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the black box warning on all labeling, advertising, and promotional materials for ovarian adnexal mass assessment score test system devices is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public." (see 5 CFR 1320.3(c)(2)).

#### **VII. What are the federalism impacts of this proposed rule?**

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to "construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain State requirements "different from or in addition to" certain Federal requirements applicable to devices (21

U.S.C. 360k; See *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). If this proposed rule is made final, the final rule would create a requirement under 21 U.S.C. 360k for a black box warning statement that must appear in all advertising, labeling, and promotional material for ovarian adnexal mass assessment score test systems.

#### **VIII. How do you submit comments on this proposed rule?**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects in 21 CFR Part 866**

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 866 as follows.

#### **PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES**

1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. In § 866.6050 of subpart G, add new paragraph (c) to read as follows:

##### **§ 866.6050 Ovarian adnexal mass assessment score test system.**

\* \* \* \* \*

(c) *Black Box Warning.* Under section 520(e) of the Federal Food, Drug, and Cosmetic Act these devices are subject to the following restriction: A warning statement must be placed in a black box and must appear in all advertising, labeling, and promotional material for these devices. That warning statement must read:

PRECAUTION: The [test name] should not be used without an independent clinical/radiological evaluation and is **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the [test name] carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

Dated: March 16, 2011.

**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-6621 Filed 3-22-11; 8:45 am]

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## DEPARTMENT OF STATE

### 22 CFR Part 123

[Public Notice: 7384]

RIN 1400-AC71

#### **International Traffic in Arms Regulations: Exemption for Temporary Export of Chemical Agent Protective Gear**

**AGENCY:** Department of State.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of State is proposing to amend the International Traffic in Arms Regulations (ITAR) to add an exemption for the temporary export of chemical agent protective gear for exclusive personal use to destinations not subject to restrictions and to Afghanistan and Iraq under specified conditions. Additionally, an exemption for firearms and ammunition is clarified by removing certain extraneous language that does not change the meaning of the exemption.

**DATES:** The Department of State will accept comments on this proposed rule until May 23, 2011.

**ADDRESSES:** Interested parties may submit comments within 60 days of the date of the publication by any of the following methods:

- *E-mail:*

*DDTCResponseTeam@state.gov*, with the subject line, "Regulatory Change—Section 123.17."

- *Mail:* Department of State,

Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change—Section 123.17, SA-1, 12th Floor, Washington, DC 20522-0112.

- *Internet:* View this notice by going to the regulations.gov Web site at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Nicholas Memos, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663-2804, or Fax (202) 261-8199; e-mail *memosni@state.gov*. ATTN: Regulatory Change, Sec. 123.17.

**SUPPLEMENTARY INFORMATION:** U.S.

individuals are traveling to hazardous areas in foreign countries where they need to wear body armor or chemical agent protective gear for personal safety. In August 2009, the ITAR was amended to provide an exemption for the temporary export of body armor covered by 22 CFR 121.1, Category X(a)(1). Now, the Department of State is proposing to amend the ITAR at §§ 123.17(f) and (g) to add an exemption for the temporary export of chemical agent protective gear covered by 22 CFR 121.1, Category XIV(f)(4). The proposed exemption will be available for temporary exports to countries not subject to restrictions under ITAR § 126.1 and to Afghanistan and Iraq under specified conditions. In order to use the exemption, the chemical agent protective gear must be for the individual's exclusive use and must be returned to the United States. The individual may not re-export the protective gear to a foreign person or otherwise transfer ownership. The protective gear may not be exported to any country where the importation would be in violation of that country's laws.

In the event the chemical agent protective gear is lost, stolen or otherwise not returned to the United States with the individual that temporarily exported the gear, a detailed report about the incident must be submitted to the Office of Defense Trade Controls Compliance. If the chemical agent protective gear is lost, the report should describe all attempts to locate the gear and explain the circumstances leading to its loss. In the event the chemical agent protective gear is used

and disposed according to HAZMAT guidelines, the report should provide a disposal date and location details for the approved HAZMAT facility used, along with a receipt for disposal services. If a HAZMAT facility is not available, the report should describe the date, location and method used to dispose of the protective gear.

The proposed change removes at (g)(2) the requirement that assistance to the government of Iraq be "humanitarian" to more accurately match the language of United Nations Security Council restrictions, which do not limit assistance to humanitarian assistance.

Section (c)(3) is to be revised to remove what is in practice extraneous language. Subject to the requirements of (c)(1)–(3), the exemption applies to all eligible individuals (with the noted exceptions). Thus, while the text is revised, the meaning of (c)(3) is not changed.

#### **Regulatory Analysis and Notices**

##### *Administrative Procedure Act*

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from section 553 (Rulemaking) and section 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department is publishing this rule with a 60-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

##### *Regulatory Flexibility Act*

Since this proposed amendment is not subject to the notice and comment procedures of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.