date of injury is the date on which the individual was hurt.

(2) *Occupational disease or infection.* Occupational illnesses and infections generally involve delayed onset of symptoms following exposure to a harmful workplace substance or condition. If the individual claims compensation for an occupational illness or infection, the date of injury is the date the individual was exposed to the substance or condition.

(3) *Hearing loss.* If the individual claims compensation for hearing loss, the date of injury is the date the individual was exposed to harmful workplace noise or other stimulus that is capable of causing hearing loss.

(4) *Death-benefit claims.* If the individual claims compensation for an employee's death, the date of injury is the date of the workplace event or incident that caused, hastened, or contributed to the death.

(5) *Cumulative trauma.* If the individual claims compensation for cumulative trauma, in which multiple traumas contribute to an overall medical condition, such as a neck condition resulting from repetitive motion, the date of injury is any date on which a workplace trauma worsened the individual's condition. A workplace event will not be deemed a contributing trauma if a corresponding worsening of the condition is due solely to its natural progression, rather than the workplace event.

(b) If the date of injury is before February 17, 2009, the individual's entitlement is governed by section 2(3)(F) as it existed prior to the 2009 amendment.

(c) If the date of injury is on or after February 17, 2009, the individual's entitlement is governed by the 2009 amendment to section 2(3)(F).

■ 8. Add § 701.505 to read as follows:

§ 701.505 May an employer stop paying benefits awarded before February 17, 2009 if the employee would now fall within the exclusion?

No. If an individual was awarded compensation for an injury occurring before February 17, 2009, the employer must still pay all benefits awarded, including disability compensation and medical benefits, even if the employee would be excluded from coverage under the amended exclusion.

Signed at Washington, DC, this 19th day of December 2011.

Gary A. Steinberg,

Acting Director, Office of Workers' Compensation Programs.

[FR Doc. 2011–32880 Filed 12–29–11; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2011–D–0028]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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.

DATES: *Effective Date:* January 30, 2012.

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 final rule?

A. Ovarian Adnexal Mass Assessment Score Test System

An ovarian adnexal mass assessment score test system is a device that measures one or more proteins in serum or plasma. It yields a single result for the likelihood that an adnexal pelvic mass in a woman for whom surgery is planned, is malignant. The test is for adjunctive use, in the context of a negative primary clinical and radiological evaluation, to augment the identification of patients whose gynecologic surgery requires oncology expertise and resources.

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 requiring 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. In the **Federal Register** of March 23, 2011 (76 FR 16292 at 12694), FDA published a final rule that classified this device into class II and established as a special control the guidance entitled ''Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System'' that recommends a black box warning to address the risk of off-label use. In the **Federal Register** of March 23, 2011 (76 FR 16425), FDA published a notice of availability of this special controls guidance document. However, 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)). In the **Federal Register** of March 23, 2011 (76 FR 16350 at 16352), FDA published a proposed rule to require the black box warning.

For devices that have significant risks that would make the devices unsafe if used inappropriately, FDA may require that the risks 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 prominent black box warning must 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 comments did FDA receive on this rule?

In the **Federal Register** of March 23, 2011 (76 FR 16350 at 16352), FDA announced the proposed rule to require the black box warning. Comments on the proposed rule were due by May 23, 2011. FDA received one comment in the docket for the proposed rule from a consumer. The comment supported the proposed rule.

IV. What is the legal authority for this final rule?

FDA is issuing this final 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 final 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)).

V. What is the environmental impact of this final 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.

VI. What is the economic impact of this final rule?

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule strengthens existing cautions against misuse of a product, the Agency certifies 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 $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final 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 final rule under section 520(e) of the FD&C Act. Through this action, the Agency requires a black box warning on product labeling, advertising, and promotional materials for ovarian adnexal mass assessment test systems. This warning will make users aware of the limitations of this device and the serious risks associated with its misuse. With the addition of this black box warning to product labeling, advertising, and marketing materials, the Agency concludes there will be a reasonable assurance of the safety and effectiveness of ovarian adnexal mass assessment test systems.

The economic impact of this final rule is expected to be very small. We are aware of a single manufacturer producing a single product that will 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 final rule 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 final rule would impose almost no cost on manufacturers. The black box warning will strengthen an existing admonition against off-label use and will not significantly affect usage. Impacts on any entities will be so small as to be difficult to quantify. For these reasons, the Agency certifies that this rule will not have a significant economic impact on a substantial number of small entities.

VII. How does the Paperwork Reduction Act of 1995 apply to this final rule?

FDA concludes that labeling provisions of this final 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)).

VIII. What are the federalism impacts of this final rule?

FDA has analyzed this final 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, Inc.* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008)). This final rule creates 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.

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 amends 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: December 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33588 Filed 12–29–11; 8:45 am]

BILLING CODE 4160–01–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Special Procedural Rules With Respect to Representation Cases Governing Periods When the National Labor Relations Board Lacks a Quorum of Members

AGENCY: National Labor Relations Board.

ACTION: Final rule.

SUMMARY: The National Labor Relations Board (the Board or the NLRB) is revising its rules governing the processing of representation cases during periods when the Board lacks a quorum of Members. This revision is being adopted to facilitate, insofar as it is possible, the normal functioning of the Agency when the number of Board Members falls below three, the number required to establish a quorum of the Board. See 29 U.S.C. 153(b); *New Process Steel* v. *NLRB,* 130 S.Ct. 2635 (2010). The effect of the revision is to enable the Agency to process some representation cases to the certification of a representative or the certification of the results of the election, while deferring Board consideration of parties' requests for review until a quorum has been restored.

DATES: Effective December 30, 2011.

FOR FURTHER INFORMATION CONTACT: Lester A. Heltzer, Executive Secretary, National Labor Relations Board, 1099 14th Street NW., Room 11600, Washington, DC 20570. Telephone (202) 273–1067 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION: The National Labor Relations Board is revising its rule requiring the automatic impoundment of ballots in representation cases when a party files a request for review. This rules revision is an addendum to the Board's December 14, 2011 rules revisions,