

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,

which added a new Subpart X to the NLRB's Rules and Regulations (29 CFR 102.178–102.181; see 76 FR 77699). The December 14 revisions covered the consideration of certain pleadings in unfair labor practice cases that require a quorum of Board Members for final action, during periods 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). In representation cases, final action on requests for review by the Board also requires a three-member quorum. The instant rule revision, which adds 29 CFR 102.182 to the NLRB's Rules and Regulations, is being adopted to facilitate, as far as possible, the expeditious processing by the Agency of representation cases during periods in which the Board lacks a quorum. No Notice of Proposed Rulemaking (NPRM) is required with respect to this rules revision, as it falls under the Administrative Procedure Act's exception to the NPRM requirement for regulatory actions involving agency *organization, procedure, or practice*. See 5 U.S.C. 553. In addition, the Agency finds that notice and comment would be impracticable within the meaning of 5 U.S.C. 5553(b)(3)(B) before the Board loses a quorum on January 3, 2012, as now appears possible.

At present, the NLRB's Rules and Regulations provide only for the adjudication of representation cases and the issuance of decisions on review by the Board when it is composed of three or more members, which constitutes the Congressionally-designated quorum of the Board. In *New Process Steel v. NLRB*, *supra*, 130 S. Ct. 2635, the Supreme Court held that Congress empowered the Board to delegate its powers to no fewer than three members, and that, to maintain a valid quorum, a membership of three must be maintained. *Id.* at 2640. It can be anticipated that, from time to time, the number of individuals appointed by the President and confirmed by Congress to serve as members of the Board may fall below three. Current Section 102.67(b) of the NLRB's Rules and Regulations requires that all ballots cast in a representation election be impounded whenever the Board has not acted on a pending request for review, thus halting the processing of the representation case at the end of the voting, but before the ballots are counted. During periods when the Board lacks a quorum, the effect of the current rule would be to withhold information concerning the results of the election from employees

and employers, who are usually eager to know the results, until the Board regains a quorum and rules on the request for review. The investigation and adjudication of objections and determinative challenges would be delayed during the same period. And in all likelihood the request for review would ultimately be denied, as are about 85% of requests for review currently filed. If the request for review is denied, the delay of the tally and any ensuing proceedings would have served no purpose whatsoever.

The Board has determined that the purposes of the National Labor Relations Act will best be served, and the Board's Congressional mandate will best be carried out, if its rules are revised to suspend, during any period the Board lacks a quorum, the second proviso of Section 102.67(b) of the NLRB's Rules and Regulations. Section 102.67(b) provides that a decision by the Regional Director upon the record shall set forth his findings, conclusions, and order or direction. The decision of the Regional Director shall be final: *Provided, however*, that within 14 days after service thereof any party may file a request for review with the Board in Washington, DC. The Regional Director shall schedule and conduct any election directed by the decision notwithstanding that a request for review has been filed with or granted by the Board. The filing of such a request shall not, unless otherwise ordered by the Board, operate as a stay of the election or any other action taken or directed by the Regional Director: *Provided, however*, that if a pending request for review has not been ruled upon or has been granted ballots whose validity might be affected by the final Board decision shall be segregated in an appropriate manner, and all ballots shall be impounded and remain unopened pending such decision.

Thus, suspension of the automatic impoundment of ballots during periods in which the Board lacks a quorum will permit Regional Directors promptly to tally the ballots cast by bargaining unit employees. The Board anticipates that the suspension of the automatic impoundment of ballots will serve the interests of the public and the parties in the speedy resolution of representation cases by avoiding extended and unnecessary delays in the tally of ballots. In addition, the Board anticipates that, in some cases the prompt tallying of ballots and recording the results of the election will cause parties to determine that it is unnecessary to pursue a request for review. In such cases, the choice of the bargaining unit employees will be

effectuated expeditiously. Thus, the instant rules revision will provide the parties the opportunity to pursue numerous representation cases through to certification, while deferring consideration of requests for review by the Board until a quorum has been restored. The rules revision expressly preserves the Board's authority, based on a properly filed request for review, to revise or revoke any certification issued by a regional director. Member Brian E. Hayes voted against the rules revision.

Executive Order 12866

The regulatory review provisions of Executive Order 12866 do not apply to independent regulatory agencies. However, even if they did, the proposed changes in the Board's rules would not be classified as "significant rules" under Section 6 of Executive Order 12866, because they will not result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or foreign markets. Accordingly, no regulatory impact assessment is required.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for procedural rules, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) pertaining to regulatory flexibility analysis do not apply to these rules. However, even if the Regulatory Flexibility Act were to apply, the NLRB certifies that these rules will not have a significant economic impact on a substantial number of small business entities as they merely provide parties with avenues for expeditiously resolving certain representation cases before the Board.

Paperwork Reduction Act

These rules are not subject to Section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501) since they do not contain any new information collection requirements.

Small Business Regulatory Enforcement Fairness Act

Because these rules relate to Agency procedure and practice and merely modify the Agency's internal processing of ballots in representation cases, the Board has determined that the Congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801) do not apply.

List of Subjects in 29 CFR Part 102

Administrative practice and procedure; Labor-management relations.

Accordingly, the Board amends 29 CFR part 102 as follows:

PART 102—RULES AND REGULATIONS, SERIES 8

■ 1. The authority citation for 29 CFR part 102 continues to read as follows:

Authority: Section 6, National Labor Relations Act, as amended (29 U.S.C. 151, 156). Section 102.117 also issued under Section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)). Sections 102.143 through 102.155 also issued under Section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

Subpart X—Special Procedures When the Board Lacks a Quorum

■ 2. Add § 102.182 to subpart X to read as follows:

§ 102.182 Representation Cases Should Be Processed to Certification.

During any period when the Board lacks a quorum, the second proviso of § 102.67(b) regarding the automatic impounding of ballots shall be suspended. To the extent practicable, all representation cases should continue to be processed and the appropriate certification should be issued by the Regional Director notwithstanding the pendency of a request for review, subject to revision or revocation by the Board pursuant to a request for review filed in accordance with this subpart.

Signed in Washington, DC, on December 28, 2011.

Mark Gaston Pearce,
Chairman.

[FR Doc. 2011-33668 Filed 12-29-11; 8:45 am]

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NATIONAL LABOR RELATIONS BOARD**29 CFR Part 104**

RIN 3142-AA07

Notification of Employee Rights Under the National Labor Relations Act

AGENCY: National Labor Relations Board.

ACTION: Final rule; delay of effective date.

SUMMARY: On August 30, 2011, the National Labor Relations Board (Board) published a final rule requiring employers, including labor organizations in their capacity as employers, subject to the National Labor Relations Act (NLRA) to post notices informing their employees of their rights as employees under the NLRA. (76 FR 54006, August 30, 2011.) On October 12, 2011, the Board amended that rule to delay the effective date from November 14, 2011, to January 31, 2012. (76 FR 63188, October 12, 2011.) The Board hereby further amends that rule to delay the effective date from January 31, 2012, to April 30, 2012. The purpose of this amendment is to facilitate the resolution of the legal challenges with respect to the rule.

DATES: This amendment is effective December 30, 2011. The effective date of the final rule published at 76 FR 54006, August 30, 2011, and amended at 76 FR 63188, October 12, 2011, is delayed from January 31, 2012 to April 30, 2012.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: On August 30, 2011, the National Labor Relations Board published a final rule requiring employers, including labor organizations in their capacity as employers, subject to the National Labor Relations Act (NLRA) to post notices informing their employees of their rights as employees under the NLRA. The Board subsequently determined that in the interest of ensuring broad voluntary compliance with the rule concerning notification of employee rights under the National Labor Relations Act, further public education and outreach efforts would be helpful. Accordingly, the Board changed the effective date of the rule from November 14, 2011, to January 31, 2012, in order to allow time for such an education and outreach effort. On December 19, 2011, the U.S. District Court for the District of

Columbia requested that the Board consider postponing the effective date of the rule in connection with a pending proceeding concerning the rule. The Board has determined that postponing the effective date of the rule would facilitate the resolution of the legal challenges that have been filed with respect to the rule. Accordingly, the Board has decided to change the effective date of the rule from January 31, 2012 to April 30, 2012.

Signed in Washington, DC, on December 23, 2011.

Mark Gaston Pearce,
Chairman.

[FR Doc. 2011-33571 Filed 12-29-11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R09-OAR-2011-0638; FRL-9612-8]

Approval and Promulgation of Air Quality Implementation Plans; California; Determinations of Failure To Attain the One-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is taking final action to determine that three areas in California, previously designated nonattainment for the now-revoked one-hour ozone national ambient air quality standard (NAAQS), did not attain that standard by their applicable attainment dates: the Los Angeles-South Coast Air Basin Area ("South Coast"), the San Joaquin Valley Area ("San Joaquin Valley"), and the Southeast Desert Modified Air Quality Maintenance Area ("Southeast Desert"). These determinations are based on three years of quality-assured and certified ambient air quality monitoring data for the period preceding the applicable attainment deadline.

DATES: *Effective Date:* This rule is effective on January 30, 2012.

ADDRESSES: EPA has established docket number EPA-R09-OAR-2011-0638 for this action. The index to the docket is available electronically at www.regulations.gov and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in