## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 4

**[Docket No. FDA–2008–N–0424]**

**RIN 0910–AF82**

## Postmarketing Safety Reporting for Combination Products; Extension of Comment Period

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

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 29, 2009, the comment period for the proposed rule that appeared in the **Federal Register** of October 1, 2009. In the proposed rule, FDA requested comments on postmarketing safety reporting requirements for combination products. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** The comment period for the proposed rule published October 1, 2009 (74 FR 50744), is extended. Submit written or electronic comments by January 29, 2010.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2008–N–0424 and/or RIN number 0910–AF82, 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions*: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. 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:** John Barlow Weiner, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of October 1, 2009 (74 FR 50744), FDA published a proposed rule with a 90-day comment period to request comments on postmarketing safety reporting requirements for combination products. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for postmarketing safety reporting for combination products.

The agency has received requests for a 30-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until January 29, 2010. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

### II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–29493 Filed 12–10–09; 8:45 am]

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## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

**RIN 2900–AN46**

## Notice of Information and Evidence Necessary To Substantiate Claim

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations regarding VA's duty to notify a claimant of the information and evidence necessary to substantiate a claim. The purpose of this amendment is to implement the Veterans' Benefits Improvement Act of 2008, which requires the Secretary of Veterans Affairs to prescribe in regulations requirements relating to the content of notice to be provided to claimants for veterans benefits, including different content for notice based on the type of claim filed, the type of benefits or services sought under the claim, and the general information and evidence required to substantiate the basic elements of each type of claim.

**DATES:** Comments must be received by VA on or before February 9, 2010.

**ADDRESSES:** Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll free number). Comments should indicate that they are submitted in response to ''RIN 2900–AN46—Notice of Information and Evidence to Substantiate Claim.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll free number). In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Kniffen, Chief, Regulations