DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2011–N–0527]

Preemption Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of preemption review.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has determined, after conducting a review of its existing regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the Agency to preempt State law, that three FDA regulatory preambles contain or refer to statements about preemption that are not legally justified. FDA conducted this review in response to the President's May 20, 2009, ''Memorandum for the Heads of Executive Departments and Agencies,'' which outlined the Administration's policy on preemption, in keeping with the principles in Executive Order 13132 on Federalism. The President's memorandum included a directive that such a review be conducted. FDA is also taking this opportunity to clarify certain preamble statements related to preemption resulting from express preemption provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) concerning nonprescription drugs and food labeling.

DATES: Effective October 5, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine Lorraine, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4258, Silver Spring, MD 20993, 301–796–4830.

SUPPLEMENTARY INFORMATION: On January 24, 2006 (71 FR 3922), FDA published a final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (physician labeling rule). In the preamble to the physician labeling rule, FDA discussed its views on the preemptive effect of both the regulation's codified provisions and, more generally, the FD&C Act. In addition, FDA subsequently published two final rules with preambles that referenced the preemption discussion in the physician labeling rule. *See* ''Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile'' (72 FR 73589, 73595, December 28, 2007); ''Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices'' (73 FR 49603, 49605–49606, August 22, 2008).

In its decision in *Wyeth* v. *Levine,* the Supreme Court addressed the preamble to the physician labeling rule and provided additional guidance in evaluating the preemptive effect of the FD&C Act and FDA regulations. 129 S. Ct. 1187 (2009). In this case, the Court upheld a State tort claim that was based on the manufacturer's failure to provide adequate warnings on the labeling of one of its prescription drug products. The Court held that the State claim was not preempted by the FD&C Act or FDA's labeling requirements, despite the Agency's position in the preamble to the physician labeling rule that such claims frustrate its statutory mandate.

According to the Court, FDA's position ''does not merit deference,'' in part, because it is ''at odds with what evidence we have of Congress' purposes.'' *Id.* at 1201. The Court found that Congress's ''silence on the [preemption] issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.'' *Id.* at 1200. While the Court acknowledged that ''some state-law claims might well frustrate the achievement of congressional objectives,'' it found that ''failure-to-warn claims'' such as the one at issue do not ''obstruct the federal regulation of drug labeling.'' *Id.* at 1204. The Court also noted that the manufacturer did not avail itself of FDA regulations that permit changes to a drug's labeling. *Id.* at 1996–97. And ''absent clear evidence that the FDA would not have approved'' the type of warning deemed necessary by the State claim, the Court was not willing to ''conclude that it was impossible'' for the manufacturer ''to comply with both federal and state requirements.'' *Id.* at 1198.

In light of the Supreme Court's decision in *Wyeth,* FDA has concluded that the position on preemption articulated in the preamble to the physician labeling rule, and subsequently referred to in the preambles of the other two rules cited previously in this document, cannot be justified under legal principles governing preemption. The codified provisions in these rules, however, do not include any statements about preemption and would not preempt State law beyond governing principles of preemption. FDA's conclusion about the regulatory preambles, therefore, does not affect the validity or operation of the codified provisions in these three final rules.

FDA also would like to clarify past preamble statements related to preemption resulting from certain express preemption provisions in the FD&C Act concerning nonprescription drugs and food labeling. Some preamble statements in regulations on nonprescription drugs contain the following language: ''Currently, [Section 751(a) of the FD&C Act (21 U.S.C. 379r(a))] operates to preempt States from imposing requirements related to the regulation of nonprescription drug products (See section 751(b) through (e) of the act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision) * * *. Although this final rule would have a preemptive effect, in that it would preclude States from issuing requirements related to these OTC * * * drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule, this preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties * * *.'' (See, e.g., 74 FR 9759, March 6, 2009; 73 FR 6015, February 1, 2008; 72 FR 71769, December 19, 2007; 72 FR 14669, March 29, 2007; 72 FR 9849, March 6, 2007; 71 FR 43358, August 1, 2006). This language could be read to suggest that FDA does not read section 751 of the FD&C Act as a whole and gives more significance to some provisions, e.g., subsection 751(a), than others, e.g., subsection 751(e) (which makes clear that section 751 does not affect any action under a state's product liability law). FDA now clarifies that it does read section 751 of the FD&C Act as a whole, in that each subsection must be read together with the other subsections.

In addition, FDA is now clarifying preamble statements in regulations on food labeling that contain the following language: ''Although this rule has a pre-emptive effect, in that it would preclude states from issuing any * * * requirements * * * that are not identical to those required by the final rule, this pre-emptive effect is consistent with what Congress set forth in Section 403A of the Act [21 U.S.C. 343–1].'' (See, *e.g.,* 74 FR 2443, January 15, 2009). Although this language reflects the statutory language in section 403A of the FD&C Act, as codified at 21 U.S.C. 343–1, it does not acknowledge

the applicability limitation set forth in section 6(c)(2) of the Nutrition Labeling and Education Act (NLEA), which was not codified. Section 6(c)(2) of the NLEA provided that section 403A of the FD&C Act ''shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides for a warning concerning the safety of the food or component of the food'' (Pub. L. 101–535, section 6, 104 Stat. 2353 (1990)). FDA clarifies that its past discussions of section 403A of the FD&C Act should have included the language of section 6(c)(2) of the NLEA.

Dated: September 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25479 Filed 10–4–11; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2010–1075; FRL–8880–2]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 36 chemical substances which were the subject of premanufacture notices (PMNs). Four of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 36 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on December 5, 2011. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (E.S.T.) on October 19, 2011.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before November 4, 2011 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**).

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–1075, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. *Attention:* Docket ID Number EPA–HQ–OPPT–2010–1075. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2010–1075. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (202) 564–9232; *e-mail address: moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; *telephone number:* (202) 554–1404; *e-mail address: TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also