

§ 99.403

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order a manufacturer to cease disseminating information under this part and to take corrective action if:

(1) In the case of a manufacturer that has submitted a supplemental application for the new use, FDA determines that the supplemental application does not contain adequate information for approval of the new use;

(2) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 6 months, the manufacturer has not, within the 6-month period, submitted a supplemental application for the new use;

(3) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time as FDA has determined to be appropriate under § 99.303(a) or (b), such manufacturer has not submitted the supplemental application within the certified time, or FDA, after an informal hearing, has determined that the manufacturer is not acting with due diligence to initiate or complete the studies necessary to support a supplemental application for the new use; or

(4) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time as FDA has determined to be appropriate under § 99.303(a) or (b), the manufacturer has discontinued or terminated the clinical studies that would be necessary to support a supplemental application for a new use.

(d) *Effective date of orders to cease dissemination.* An order to cease dissemination of information shall be effective upon date of receipt by the manufacturer, unless otherwise stated in such order.

(e) *Cessation of dissemination by a non-complying manufacturer.* A manufacturer that begins to disseminate information in compliance with this part, but subsequently fails to comply with this part, shall immediately cease disseminating information under this part. A manufacturer that discontinues, terminates, or fails to conduct with due diligence clinical studies that it certified it would complete under § 99.201(a)(4)(ii) shall be deemed not in compliance with this part. A manufac-

turer shall notify FDA immediately if it ceases dissemination under this paragraph.

§ 99.403 Termination of approvals of applications for exemption.

(a) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application if:

(1) The application for an exemption had been deemed to be approved because the agency had not acted on the application within 60 days after its receipt by FDA;

(2) The manufacturer is disseminating written information on the new use; and

(3) FDA determines that it would be economically and ethically possible for the manufacturer to conduct the clinical studies needed to submit a supplemental application for the new use.

(b) If FDA terminates a deemed approval of an application for an exemption under paragraph (a) of this section, FDA also may:

(1) Order the manufacturer to cease disseminating information; and

(2) Order the manufacturer to take action to correct the information that has been disseminated if FDA determines that the new use described in the disseminated information would pose a significant risk to public health.

(c) FDA shall notify the manufacturer if it terminates the deemed approval of an application for an exemption under paragraph (a) of this section. If FDA also issues an order to cease dissemination of information, the manufacturer shall comply with the order no later than 60 days after its receipt.

(d) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application for a new use if, after consulting with the manufacturer that was granted such exemption, FDA determines that the manufacturer no longer meets the requirements for an exemption on the basis that it is economically prohibitive or unethical to conduct the studies needed to submit a supplemental application for the new use.

(e) If FDA terminates an approval of an application for an exemption under

paragraph (d) of this section, the manufacturer must, within 60 days of being notified by FDA that its exemption approval has been terminated, file a supplemental application for the new use that is the subject of the information being disseminated under the exemption, certify, under § 99.201(a)(4)(i) or (a)(4)(ii) that it will file a supplemental application for the new use, or cease disseminating the information on the new use. FDA may require a manufacturer that ceases dissemination of information on the new use to undertake corrective action.

§ 99.405 Applicability of labeling, adulteration, and misbranding authority.

The dissemination of information relating to a new use for a drug or device may constitute labeling, evidence of a new intended use, adulteration, or misbranding of the drug or device if such dissemination fails to comply with section 551 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa) and the requirements of this part. A manufacturer's failure to exercise due diligence in submitting the clinical studies that are necessary for the approval of a new use that is the subject of information disseminated under this part or in beginning or completing such clinical studies shall be deemed a failure to comply with section 551 of the act and the requirements of this part.

Subpart F—Recordkeeping and Reports

§ 99.501 Recordkeeping and reports.

(a) A manufacturer disseminating information under this part shall:

(1) Maintain records sufficient to allow the manufacturer to take corrective action as required by FDA. The manufacturer shall make such records available to FDA, upon request, for inspection and copying. Such records shall either:

(i) Identify, by name, those persons receiving the disseminated information; or

(ii) Identify, by category, the recipients of the disseminated information, unless FDA requires the manufacturer to retain records identifying individual

recipients of the disseminated information. Manufacturers whose records identify recipients by category only shall:

(A) Identify subcategories of recipients where appropriate (e.g., oncologists, pediatricians, obstetricians, etc.); and

(B) Ensure that any corrective action to be taken will be sufficiently conspicuous to individuals within that category of recipients;

(2) Maintain an identical copy of the information disseminated under this part; and

(3) Upon the submission of a supplemental application to FDA, notify the appropriate office identified in § 99.201(c) of this part.

(b) A manufacturer disseminating information on a new use for a drug or device shall, on a semiannual basis, submit to the FDA office identified in § 99.201(c) of this part:

(1) A list containing the titles of articles and reference publications relating to the new use of drugs or devices that the manufacturer disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency. The list shall cover articles and reference publications disseminated in the 6-month period preceding the date on which the manufacturer provides the list to FDA;

(2) A list identifying the categories of health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or Federal or State Government agencies that received the articles and reference publications in the 6-month period described in paragraph (b)(1) of this section. The list shall also identify which category of recipients received a particular article or reference publication;

(3) A notice and summary of any additional clinical research or other data relating to the safety or effectiveness of the new use, and, if the manufacturer possesses such clinical research or other data, a copy of the research or data. Such other data may include, but is not limited to, new articles published in scientific or medical journals, reference publications, and summaries of adverse effects that are or may be associated with the new use;