

**Food and Drug Administration, HHS**

**§ 12.45**

the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

**§ 12.38 Effective date of an order.**

(a) If a person who is subject to a notice of opportunity for hearing under §12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA, NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under §12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

**Subpart C—Appearance and Participation**

**§ 12.40 Appearance.**

(a) A person who has filed a notice of participation under §12.45 may appear in person or by counsel or other representative in any hearing and, subject to §12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in §12.90.

**§ 12.45 Notice of participation.**

(a) Within 30 days after publication of the notice of hearing under §12.35, a person desiring to participate in a hearing is to file with the Dockets Management Staff under §10.20 a notice of participation in the following form:

(Date)

Dockets Management Staff, Food and Drug Administration, Department of Health and

Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**NOTICE OF PARTICIPATION**

Docket No. \_\_\_\_

Under 21 CFR part 12, please enter the participation of:

(Name) \_\_\_\_\_  
(Street address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
(Telephone number) \_\_\_\_\_

Service on the above will be accepted by:

(Name) \_\_\_\_\_  
(Street address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
(Telephone number) \_\_\_\_\_

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) \_\_\_\_\_

(b) An amendment to a notice of participation should be filed with the Dockets Management Staff and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for non-participation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by §12.85 or the prehearing order issued under §12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

[44 FR 22339, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 68 FR 24879, May 9, 2003]