

the conclusion of the person's presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer for response by a person making a presentation.

(f) *Judicial review.* The Commissioner's decision constitutes final agency action from which the applicant may petition for judicial review. Before requesting an order from a court for a stay of action pending review, an applicant must first submit a petition for a stay of action under §10.35 of this chapter.

§314.540 Postmarketing safety reporting.

Drug products approved under this program are subject to the postmarketing recordkeeping and safety reporting applicable to all approved drug products, as provided in §§314.80 and 314.81.

§314.550 Promotional materials.

For drug products being considered for approval under this subpart, unless otherwise informed by the agency, applicants must submit to the agency for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

§314.560 Termination of requirements.

If FDA determines after approval that the requirements established in §314.520, §314.530, or §314.550 are no longer necessary for the safe and effective use of a drug product, it will so notify the applicant. Ordinarily, for drug products approved under §314.510, these requirements will no longer apply when FDA determines that the required postmarketing study verifies and describes the drug product's clinical benefit and the drug product would be ap-

propriate for approval under traditional procedures. For drug products approved under §314.520, the restrictions would no longer apply when FDA determines that safe use of the drug product can be assured through appropriate labeling. FDA also retains the discretion to remove specific post-approval requirements upon review of a petition submitted by the sponsor in accordance with §10.30.

PART 316—ORPHAN DRUGS

Subpart A—General Provisions

Sec.

- 316.1 Scope of this part.
- 316.2 Purpose.
- 316.3 Definitions.
- 316.4 Address for submissions.

Subpart B—Written Recommendations for Investigations of Orphan Drugs

- 316.10 Content and format of a request for written recommendations.
- 316.12 Providing written recommendations.
- 316.14 Refusal to provide written recommendations.

Subpart C—Designation of an Orphan Drug

- 316.20 Content and format of a request for orphan-drug designation.
- 316.21 Verification of orphan-drug status.
- 316.22 Permanent-resident agent for foreign sponsor.
- 316.23 Timing of requests for orphan-drug designation; designation of already approved drugs.
- 316.24 Granting orphan-drug designation.
- 316.25 Refusal to grant orphan-drug designation.
- 316.26 Amendment to orphan-drug designation.
- 316.27 Change in ownership of orphan-drug designation.
- 316.28 Publication of orphan-drug designations.
- 316.29 Revocation of orphan-drug designation.
- 316.30 Annual reports of holder of orphan-drug designation.

Subpart D—Orphan-drug Exclusive Approval

- 316.31 Scope of orphan-drug exclusive approval.
- 316.34 FDA recognition of exclusive approval.
- 316.36 Insufficient quantities of orphan drugs.