questions to be submitted to the presiding officer for response by a person making a presentation.

(f) Judicial review. The Commissioner of Food and Drugs’ 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.

§315.3 Postmarketing safety reporting.

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

§315.4 Indications.

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.

§315.5 Evaluation of effectiveness.

FDA’s determination of the safety and effectiveness of a diagnostic radiopharmaceutical includes consideration of the following:

(a) An article that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans and that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(b) Any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of such article as defined in paragraph (a) of this section.

§315.6 Evaluation of safety.

For purposes of this part, diagnostic radiopharmaceutical means:


SOURCE: 64 FR 26667, May 17, 1999, unless otherwise noted.