Food and Drug Administration, HHS

§ 601.30 Scope.

(c) Status reports. A statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant. The statement shall include whether postmarketing clinical studies in pediatric populations were required or agreed to, and, if so, the status of these studies shall be reported to FDA in annual progress reports of postmarketing studies under §601.70 rather than under this section.


§ 601.29 Guidance documents.

(a) FDA has made available guidance documents under §10.115 of this chapter to help you comply with certain requirements of this part.

(b) The Center for Biologics Evaluation and Research (CBER) maintains a list of guidance documents that apply to the center’s regulations. The lists are maintained on the Internet and are published annually in the FEDERAL REGISTER. You may request a copy of the CBER list from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration (see mailing addresses in §600.2 of this chapter).

[65 FR 56480, Sept. 19, 2000, as amended at 70 FR 14984, Mar. 24, 2005]

Subpart D—Diagnostic Radiopharmaceuticals

SOURCE: 64 FR 26668, May 17, 1999, unless otherwise noted.

§ 601.30 Scope.

This subpart applies to radiopharmaceuticals intended for in vivo administration for diagnostic and monitoring use. It does not apply to radiopharmaceuticals intended for therapeutic purposes. In situations where a particular radiopharmaceutical is proposed for both diagnostic and therapeutic uses, the radiopharmaceutical must be evaluated taking into account each intended use.