§ 316.50 Guidance documents.

FDA’s Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the Federal Register. A request for a copy of the list should be directed to the Office of Orphan Products Development (HF-35), Food and Drug Administration, HHS.

Subpart E—Open Protocols for Investigations

§ 316.40 Treatment use of a designated orphan drug.

Prospective investigators seeking to obtain treatment use of designated orphan drugs may do so as provided in subpart I of this chapter.

[74 FR 40945, Aug. 13, 2009]

§ 316.50 Availability of information

FDA’s Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the Federal Register. A request for a copy of the list should be directed to the Office of Orphan Products Development (HF-35), Food and Drug Administration, HHS.