

be made as a request for a waiver under § 600.90.

[59 FR 54042, Oct. 27, 1994, as amended at 64 FR 56449, Oct. 20, 1999]

§ 600.90 Waivers.

(a) A licensed manufacturer may ask the Food and Drug Administration to waive under this section any requirement that applies to the licensed manufacturer under §§ 600.80 and 600.81. A waiver request under this section is required to be submitted with supporting documentation. The waiver request is required to contain one of the following:

(1) An explanation why the licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) A description of an alternative submission that satisfies the purpose of the requirement, or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) The licensed manufacturer's alternative submission satisfies the requirement, or

(3) The licensed manufacturer's submission otherwise justifies a waiver.

PART 601—LICENSING

Subpart A—General Provisions

Sec.

601.2 Applications for biologics licenses; procedures for filing.

601.4 Issuance and denial of license.

601.5 Revocation of license.

601.6 Suspension of license.

601.7 Procedure for hearings.

601.8 Publication of revocation.

601.9 Licenses; reissuance.

Subpart B [Reserved]

Subpart C—Biologics Licensing

601.12 Changes to an approved application.

601.15 Foreign establishments and products: Samples for each importation.

601.20 Biologics licenses; issuance and conditions.

601.21 Products under development.

601.22 Products in short supply; initial manufacturing at other than licensed location.

601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

601.26 Reclassification procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

601.27 Pediatric studies.

601.28 Annual reports of postmarketing pediatric studies.

601.29 Guidance documents.

Subpart D—Diagnostic Radiopharmaceuticals

601.30 Scope.

601.31 Definition.

601.32 General factors relevant to safety and effectiveness.

601.33 Indications.

601.34 Evaluation of effectiveness.

601.35 Evaluation of safety.

Subpart E—Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses

601.40 Scope.

601.41 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.

601.42 Approval with restrictions to assure safe use.

601.43 Withdrawal procedures.

601.44 Postmarketing safety reporting.

601.45 Promotional materials.

601.46 Termination of requirements.

Subpart F—Confidentiality of Information

601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

601.51 Confidentiality of data and information in applications for biologics licenses.

G—Postmarketing Studies

601.70 Annual progress reports of postmarketing studies.

AUTHORITY: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

EFFECTIVE DATE NOTE: At 65 FR 64618, Oct. 30, 2000, the authority citation for 21 CFR part 601 was revised, effective Feb. 27, 2001.