

Food and Drug Administration, HHS

§ 5.70

§ 5.66 Approval of schools providing food-processing instruction.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(b) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(c) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

The Center Director and Deputy Center Directors, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(e) Notice of license suspensions under § 601.6 of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989; 56 FR 25025, June 3, 1991; 64 FR 47669, Sept. 1, 1999; 64 FR 56448, Oct. 20, 1999]

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the