Food and Drugs

21

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PARTS 600 TO 1299

Revised as of April 1, 1978

CONTAINING
A CODIFICATION OF DOCUMENTS OF GENERAL APPLICABILITY AND FUTURE EFFECT

AS OF APRIL 1, 1978

With Ancillaries

Published by
the Office of the Federal Register
National Archives and Records Service
General Services Administration

as a Special Edition of
the Federal Register

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE—(Continued)

(Parts 600-1299)

SUBCHAPTER F—BIOLOGICS

SUBCHAPTER G—COSMETICS

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of Part 20 of this chapter.

(7) All records showing the manufacturer's testing of a particular lot, after deletion of data or information that would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 20.61 of this chapter.

(8) All records showing the testing of and action on a particular lot by the Food and Drug Administration.

(f) The following data and information in a biological product file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(g) For purposes of this regulation, safety and effectiveness data include all studies and tests of a biological product on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

[39 FR 44656, Dec. 24, 1974, as amended at 42 FR 15676, Mar. 22, 1977]

PART 606—CURRENT GOOD MANUFACTURING PRACTICES FOR BLOOD AND BLOOD COMPONENTS

Subpart A—General Provisions

Subpart B—Organization and Personnel

Subpart C—Plant and Facilities

Subpart D—Equipment

Subpart E—[Reserved]

Subpart F—Production and Process Controls

Subpart G—Finished Product Control

Subpart H—Laboratory Controls

Subpart I—Records and Reports

AUTHORITY: Secs. 201, 501, 502, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended by 76 Stat. 780, 1055–1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87-781 (21 U.S.C. 321, 351, 352, 360 and note, 371), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 as amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4 and 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)).

SOURCE: 40 FR 53532, Nov. 18, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 606.3 Definitions.

As used in this part:

sion shall not apply to Source Plasma (Human).

(10) Quantity of source material, and the kind and quantity of anticoagulant.

(11) Additives and cryoprotective agents added to the product that may still be present.

(12) Results of all tests performed when necessary for safe and effective use.

(13) The statement: "Caution: For Manufacturing Use Only", where applicable.

(14) The immunizing antigen used or the antibody present for products for further manufacturing, when applicable.

[40 FR 53532, Nov. 18, 1975, as amended at 43 FR 2147, Jan. 13, 1978]

EFFECTIVE DATE NOTE: At 43 FR 2147, Jan. 13, 1978, in § 606.120, paragraphs (b)(2) through (b)(13) were redesignated as paragraphs (b)(3) through (b)(14), and a new paragraph (b)(2) was added, effective May 15, 1978.

Subpart H—Laboratory Controls

§ 606.140 Laboratory controls.

Laboratory control procedures shall include:

(a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

(b) Adequate provisions for monitoring the reliability, accuracy, precision and performance of laboratory test procedures and instruments.

(c) Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.

§ 606.151 Compatibility testing.

Standard operating procedures for compatibility testing shall include the following:

(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

(b) The use of fresh recipient serum samples less than 48 hours old for all pretransfusion testing.

(c) The testing of the donor's cells with the recipient's serum (major crossmatch) by a method that will demonstrate agglutinating, coating and hemolytic antibodies, which shall include the antiglobulin method.

(d) A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate.

(e) Procedures to expedite transfusions in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by the physician requesting the procedure.

Subpart I—Records and Reports

§ 606.160 Records.

(a)(1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.