

§ 114.8 Outline of Production required.

An Outline of Production shall be on file with Animal and Plant Health Inspection Service for each licensed biological product or for each biological product authorized to be imported into the United States for Distribution and Sale. Preparation of a biological product in a licensed establishment shall be in accordance with the Outline of Production for such product filed with Animal and Plant Health Inspection Service as provided in this section, but subject to changes as may be required under § 114.8(f).

(a) The Outline of Production shall be prepared as prescribed in § 114.9 and submitted to Animal and Plant Health Inspection Service for filing. When objectionable features, if any, are corrected and no further exceptions are taken by Animal and Plant Health Inspection Service to an Outline of Production for a biological product, such Outline of Production shall be approved for filing.

(b) Each page shall be stamped as filed on the date such action was taken in the bottom right hand corner. Although the filed outline may be referred to as an approved outline, approval for filing constitutes no endorsement by Animal and Plant Health Inspection Service of such biological product or the methods and procedures used to prepare such biological product.

(c) The original and two copies shall be retained by Animal and Plant Health Inspection Service and the remaining copies returned.

(d) Each licensee shall review each Outline of Production for accuracy and sufficiency not less frequently than once a year. Revisions necessary to bring an Outline of Production into compliance with the regulations shall be submitted to Animal and Plant Health Inspection Service.

(e) When a list of licensed products to be continued in production at a licensed establishment is requested by the Administrator in accordance with § 102.5(d) of this subchapter, the licensee shall supplement the list with information for each product as follows:

(1) The Outline of Production currently being used shall be identified as

to the date when last revised and filed with Animal and Plant Health Inspection Service and the date of the last review made by the licensee.

(2) The Outline of Production to be kept in the active file shall be designated. If more than one has been filed for a product, only the Outline of Production currently being used shall be included.

(f) The Administrator may, upon the basis of information not available to him at the time the current Outline of Production for a biological product was filed, object to the methods or procedures being used in the preparation of such biological product and notify the licensee to modify the filed Outline of Production to eliminate such objections. If the licensee does not comply with the notice, the Administrator may, after affording opportunity for a hearing to the licensee, suspend the product license for the biological product involved; in which case, the licensee shall not prepare such product until subsequent notice of withdrawal of the suspension is given to the licensee.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991]

§ 114.9 Outline of Production guidelines.

Each Outline of Production shall be prepared in accordance with the applicable directions provided in this section.

(a) *General requirements.* (1) The original and not more than four copies of each Outline of Production or special outline or revised pages of either shall be prepared on heavy paper (8.5" x 11") of a type receptive to permanent stamp ink.

(2) The name of the biological product (or component), the establishment license number, and the date prepared shall appear on a front cover page and each page of the Outline of Production or special outline. The name of the licensee (or foreign manufacturer) shall appear on the front cover page.