§ 600.81 Distribution reports.

The licensed manufacturer shall submit to the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research (see mailing addresses in §600.2), information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. The interval between distribution reports shall be 6 months. Upon written notice, FDA may require that the licensed manufacturer submit distribution reports under this section at times other than every 6 months. The distribution report shall consist of the bulk lot number (from which the final container was filled), the fill lot numbers for the total number of dosage units of each strength or potency distributed (e.g., fifty thousand per 10-milliliter vials), the label lot number (if different from fill lot number), labeled date of expiration, number of doses in fill lot/label lot, date of release of fill lot/label lot for distribution at that time. If any significant amount of a fill lot/label lot is returned, include this information. Disclosure of financial or pricing data is not required. As needed, FDA may require submission of more detailed product distribution information. Upon written notice, FDA may require that the licensed manufacturer submit reports under this section at times other than those stated. Requests by a licensed manufacturer to submit reports at times other than those stated should be made as a request for a waiver under §600.90.


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.
601.14 Regulatory submissions in electronic format.
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.

§ 600.80 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.