(d) **Exemptions.** Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, issued by the Director, Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research.


Subpart G—Labeling Standards

§ 610.60 Container label.

(a) **Full label.** The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

1. The proper name of the product;
2. The name, address, and license number of manufacturer;
3. The lot number or other lot identification;
4. The expiration date;
5. The recommended individual dose, for multiple dose containers.
6. The statement: ‘‘‘Rx only’’’ for prescription biologics.
§ 610.61  Package label.

The following items shall appear on the label affixed to each package containing a product:

(a) The proper name of the product;
(b) The name, address, and license number of manufacturer;
(c) The lot number or other lot identification;
(d) The expiration date;
(e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words “no preservative”;
(f) The number of containers, if more than one;
(g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;
(h) The recommended storage temperature;
(i) The words “Shake Well”, “Do not Freeze” or the equivalent, as well as other instructions, when indicated by the character of the product;
(j) The recommended individual dose if the enclosed container(s) is a multiple-dose container;
(k) The route of administration recommended, or reference to such directions in an enclosed circular;
(l) Known sensitizing substances, or reference to an enclosed circular containing appropriate information;
(m) The type and calculated amount of antibiotics added during manufacture;
(n) The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;
(o) The adjuvant, if present;
(p) The source of the product when a factor in safe administration;
(q) The identity of each microorganism used in manufacture, and, where applicable, the production medium and the method of inactivation, or reference to an enclosed circular containing appropriate information;
(r) Minimum potency of product expressed in terms of official standard of potency or, if potency is a factor and no U.S. standard of potency has been prescribed, the words “No U.S. standard of potency.”
(s) The statement: “Rx only” for prescription biologicals.

§ 610.62  Proper name; package label; legible type.

(a) Position. The proper name of the product on the package label shall be placed above any trademark or trade