§ 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 biologicals.

(b) Package label information. If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.

(c) Partial label. If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.

(d) No container label. If the container is incapable of bearing any label, the items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label.

(e) Visual inspection. When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

(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

§ 610.61 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 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