manufactured from a feed additive premix, feed additive concentrate, or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing a quantitative composition statement of its antibiotic content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive premix, concentrate, or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(iv) The medicated feed contains only, as the drug component (or components), a drug (or drugs) as provided by and in accordance with the regulations in Part 121 of this chapter; it was manufactured from a feed additive concentrate or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing the quantitative composition of its drug content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive concentrate or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(v) The medicated feed contains only drug components as provided by and in accordance with the regulations in Part 121 of this chapter and was manufactured from a feed additive supplement, a low level growth-promotion antibiotic premix, a low level growth-promotion antibiotic concentrate, a feed additive concentrate, or a combination of any two of these used in accordance with the conditions set forth in subdivisions (ii), (iii), and (iv) of this subparagraph.

(g) Production and control procedures shall include provision for discontinuing distribution of any medicated feed found by the assay procedures, or any other controls performed, to fail to conform to appropriate specifications. Distribution of subsequent production shall not begin until it has been determined that proper control procedures have been established.

§ 133.107 Packaging and labeling.

Packaging and labeling operations shall be adequately performed and controlled to assure that only those medicated feeds made in compliance with established formula records and manufacturing and control directions shall be distributed; to prevent mixups between the medicated feeds during the packaging and labeling operations; and to assure that correct labeling is employed for the medicated feed. In the case of medicated feeds distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of an invoice or placard identifying the medicated feed and bearing adequate information for the safe and effective use of the medicated feed. Labels and labeling shall be received, handled, and stored in a manner that avoids labeling mixups. Previously used containers shall be adequately cleaned and labeled before reuse to avoid adulteration or misbranding.

§ 133.108 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that the drug components and the finished medicated feeds conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications and a description of the test procedures used to check them for each kind of drug used in the manufacture of medicated feeds; this may consist of the manufacturer's or supplier's statement of specifications.

(b) The establishment of finished-product specifications for medicated feeds and a description of any necessary laboratory test procedures to check them, including methods of assay for the active drug ingredient.

(c) A determination that the drug components remain uniformly dispersed and stable in the medicated feed under ordinary conditions of shipment, storage, and use; this may consist of a supplier's or consultant's determination made on a feed of substantially the same formula.

(d) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used; the official Methods of Analysis of the Association of Official Agricultural Chemists, methods described in an official compendium, and any method, submitted as a part of a food additive petition or new-drug application, which has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.