(2) If a proposed NDC conforms to the requirements of this section and is not reserved for a different drug or was not previously assigned to a different drug, FDA will assign the NDC to a drug when it receives listing information required for that drug under § 207.49 or § 207.53.

(3) A manufacturer, repacker, relabeler, or private label distributor may voluntarily reserve a proposed NDC for a drug, before the drug is listed, by submitting the following information:

(i) A proposed NDC that conforms to the requirements of this section;

(ii) The established name of the active ingredient(s) and the strength of each active ingredient in the drug; and

(iii) In the case of a finished drug product, the dosage form, and route of administration.

(4) If the required information is submitted and the proposed NDC is properly formatted and not already assigned or reserved, FDA will reserve the proposed NDC for a period of 2 years from the date of submission. If the drug for which the proposed NDC is reserved is not listed in accordance with § 207.49 or § 207.53 during such 2-year period, the reservation of the proposed NDC will lapse. FDA may also cancel the reservation of a proposed NDC at any time on the request of the person whose labeler code is included in the proposed NDC.

(e) *How must the information be submitted to us*? The information described in paragraphs (c) and (d) of this section must be submitted electronically unless FDA grants a waiver under § 207.65.

§ 207.35 What changes require a new NDC?

(a) Once an NDC has been assigned by FDA, the registrant must propose a new and unique NDC for a drug when there is a change, after the drug is initially marketed, to any of the information identified in paragraphs (b) and (c) of this section. A new NDC must be proposed to FDA for assignment through an updated listing in accordance with § 207.57.

(b) The proposed new NDC must include a new product code when there is a change to any of the following information:

(1) The drug's established name or proprietary name, if any;

(2) Any active pharmaceutical ingredient or the strength of any active pharmaceutical ingredient;

(3) The dosage form;

(4) A change in the drug's status, between prescription and nonprescription, or for animal drugs, between prescription, nonprescription, or veterinary feed directive (VFD) status;

(5) A change in the drug's intended use between human and animal; or

(6) The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any).

(c) When there is a change only to the package size or type, including the immediate unit-of-use container, if any, the proposed new NDC must include only a new package code and retain the existing product code unless all available package codes have already been combined with the existing product code in NDCs assigned by FDA.

§ 207.37 What restrictions pertain to the use of the NDC?

(a) A product may be deemed to be misbranded if an NDC is used:

(1) To represent a different drug than the drug for which the NDC has been assigned, as described in § 207.33;

(2) To denote or imply FDA approval of a drug; or

(3) On products that are not subject to parts 207, 607 of this chapter, or 1271 of this chapter, such as dietary supplements and medical devices.

(b) If marketing is resumed for a discontinued drug, and no changes have been made to the drug that would require a new NDC under § 207.35, the drug must have the same NDC that was assigned to it as described in § 207.33, before marketing was discontinued.

Subpart D—Listing

§ 207.41 Who must list drugs and what drugs must they list?

(a) Each registrant must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution. Each domestic registrant must list each such drug regardless of whether the drug enters interstate