(e) *Advertisements.* (1) A representative sampling of advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(2) If we request it for good cause, a copy of all advertisements for a particular drug described in paragraph (e)(1) of this section, including advertisements described in §202.1(l)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after our request.

(f) *Private label distributor products.* A listing submission for a human drug distributed by a private label distributor described in §207.41(c)(2) must include information specified in §207.53(b) through (e) as applicable and:

(1) The appropriate NDC(s) (as described in §207.33) that include the private label distributor's labeler code and all package code variations;

(2) The name, mailing address, telephone number, and email address of the private label distributor; and

(3) For drugs bearing the NDC(s) reported under paragraph (f)(1) of this section, labeling as described in paragraphs (d)(1) through (4) of this section, as applicable, that accompanies the private label distributor's product.

§207.54 What listing information must a registrant submit for a drug that it salvages?

A registrant who also relabels or repacks a drug that it salvages must list the drug it relabels or repacks in accordance with §207.53 rather than in accordance with this section. A registrant who performs only salvaging with respect to a drug must provide the following listing information for that drug.

(a) The NDC assigned to the drug immediately before the drug is received by the registrant for salvaging;

(b) The lot number and expiration date of the salvaged drug product; and

(c) The name and Unique Facility Identifier for each establishment where the registrant salvages the drug.

§207.55 What additional drug listing information may FDA require?

For a particular listed drug, upon our request, the registrant must briefly state the basis for its belief that the drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

§207.57 What information must registrants submit when updating listing information and when?

Registrants must review and update listing information at a minimum, as follows:

(a) Registrants must provide listing information at the time of annual establishment registration for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been listed previously.

(b) Registrants must review and update their drug listing information each June and December. When doing so, registrants must:

(1)(i) Provide listing information, in accordance with §§207.49, 207.53, and 207.54, for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been previously listed;

(ii) Submit the date that they discontinued the manufacture, repacking, relabeling or salvaging for commercial distribution of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled, or salvaged;

(iii) Submit the date that they resumed the manufacture, repacking, or relabeling for commercial distribution of a drug previously discontinued, and provide any required listing information not previously submitted; and

(iv) Submit any material changes in any information previously submitted pursuant to §§207.49, 207.53, 207.54, or other relevant sections of this part; or

(2) For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required

under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single ''no changes'' certification during the annual registration update under § 207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.

(c) Registrants are encouraged to submit listing information for every drug subject to listing under this part prior to commercial distribution and are encouraged to update listing information at the time of any change affecting information previously submitted.

Subpart E—Electronic Format for Registration and Listing

§ 207.61 How is registration and listing information provided to FDA?

(a) *Electronic format.* (1) Except as provided in § 207.65, all information submitted under this part must be transmitted to FDA in electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. We may periodically issue guidance on how to provide registration and listing information in electronic format (specifying for example method of transmission, media, file formats, preparation, and organization of files).

(2) Information provided in electronic format must comply with part 11 of this chapter, except as follows:

(i) Advertisements and labeling, including the content of labeling, required under this part are exempt from the requirements in § 11.10(a), (c) through (h), and (k) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(ii) All other information submitted under this part is exempt from the requirements in § 11.10(b), (c), and (e) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(b) *English language.* Drug establishment registration and drug listing information must be provided in the English language. The content of labeling must be provided at a minimum in the English language. Where § 201.15(c) of this chapter permits product labeling solely in a foreign language, the content of labeling must be submitted in that language along with an accurate English translation.

§ 207.65 How can a waiver of the electronic submission requirement be obtained?

(a) All information submitted under this part must be transmitted to FDA electronically in accordance with § 207.61(a) unless FDA has granted a request for waiver of this requirement prior to the date on which submission of such information is due. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. All waiver requests must be sent to: SPL Coordinator, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993.

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable.

Subpart F—Miscellaneous

§ 207.69 What are the requirements for an official contact and a United States agent?

(a) *Official contact.* Registrants subject to the registration requirements of this part must designate an official contact for each establishment. The official contact is responsible for:

(1) Ensuring the accuracy of registration and listing information; and