(g) *Failure to comply.* In addition to other remedies available in law and regulations, in the event of repeated failure of the applicant to comply with this section, FDA may require that the applicant submit a supplement for any proposed change and obtain approval of the supplement by FDA prior to distribution of the product made using the change.

(h) *Administrative review.* Under § 10.75 of this chapter, an applicant may request internal FDA review of FDA employee decisions under this section.

[62 FR 39901, July 24, 1997, as amended at 63 FR 66399, Dec. 1, 1998. Redesignated at 65 FR 59718, Oct. 6, 2000, and amended at 69 FR 18766, Apr. 8, 2004; 70 FR 14983, Mar. 24, 2005]

EFFECTIVE DATE NOTE: At 71 FR 3997, Jan. 24, 2006, § 601.12 was amended by adding two sentences after the second sentence and before the third sentence in paragraph (f)(1); revising the introductory text of paragraph (f)(2)(i); removing from paragraph (f)(3)(i)(B) the word ''and''; removing from paragraph (f)(3)(i)(C) the phrase ''Medication Guide.'' and adding in its place the phrase ''Medication Guide; and''; and adding paragraph (f)(3)(i)(D), effective June 30, 2006. For the convenience of the user, the additions and revisions follow:

§ 601.12 Changes to an approved application.

* * * * *

(f) * * *

(1) * * * An applicant cannot use paragraph (f)(2) of this section to make any change to the information required in § 201.57(a) of this chapter. An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. * * *

(2) * * *

(i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label, except for changes to the package insert required in § 201.57(a) of this chapter (which must be made pursuant to paragraph (f)(1) of this section), to accomplish any of the following:

* * * * *

(f) * * *

(3) * * *

(i) * * *

(D) A change to the information required in § 201.57(a) of this chapter as follows:

(*1*) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(*2*) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

* * * * *

§ 601.14 Regulatory submissions in electronic format.

(a) *General.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files.)

(b) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (a) of this section. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f) that require applicants to submit specimens of the labels, enclosures, and containers, or to submit other final printed labeling. Submissions under this paragraph must be made in accordance with part 11 of this chapter except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

[68 FR 69020, Dec. 11, 2003]

§ 601.15 Foreign establishments and products: samples for each importation.

Random samples of each importation, obtained by the District Director of Customs and forwarded to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter) must be at least two final containers of each lot of product. A copy of the associated documents which describe and identify the shipment must accompany the shipment for forwarding with the samples to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2). For shipments of 20 or less final containers,