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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 601

[Docket No. FDA-2006-N-0364] (formerly Docket No. 2006N-0466)

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to reincorporate a regulation that was inadvertently removed. This action is being taken to correct the regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Tiffany J. Brown, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error appeared in the agency's codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of December 28, 2007 (72 FR 73589), FDA published an interim final rule that inadvertently revised § 601.12(f)(3)(i)(D) (21 CFR 601.12(f)(3)(i)(D)) instead of adding a new paragraph, § 601.12(f)(3)(i)(E). Accordingly, § 601.12(f)(3)(i)(D), which was added in the **Federal Register** of January 24, 2006 (71 FR 3922), is being reincorporated into the regulations to replace current § 601.12(f)(3)(i)(D); current § 601.12(f)(3)(i)(D) is being redesignated as § 601.12(f)(3)(i)(E). This document corrects the errors described previously.

FDA-2006-N-0364

NFR

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 2. In § 601.12, redesignate paragraph (f)(3)(i)(D) as paragraph (f)(3)(i)(E) and add new paragraph (f)(3)(i)(D) to read as follows:

§ 601.12 Changes to an approved application.

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(f) * * *

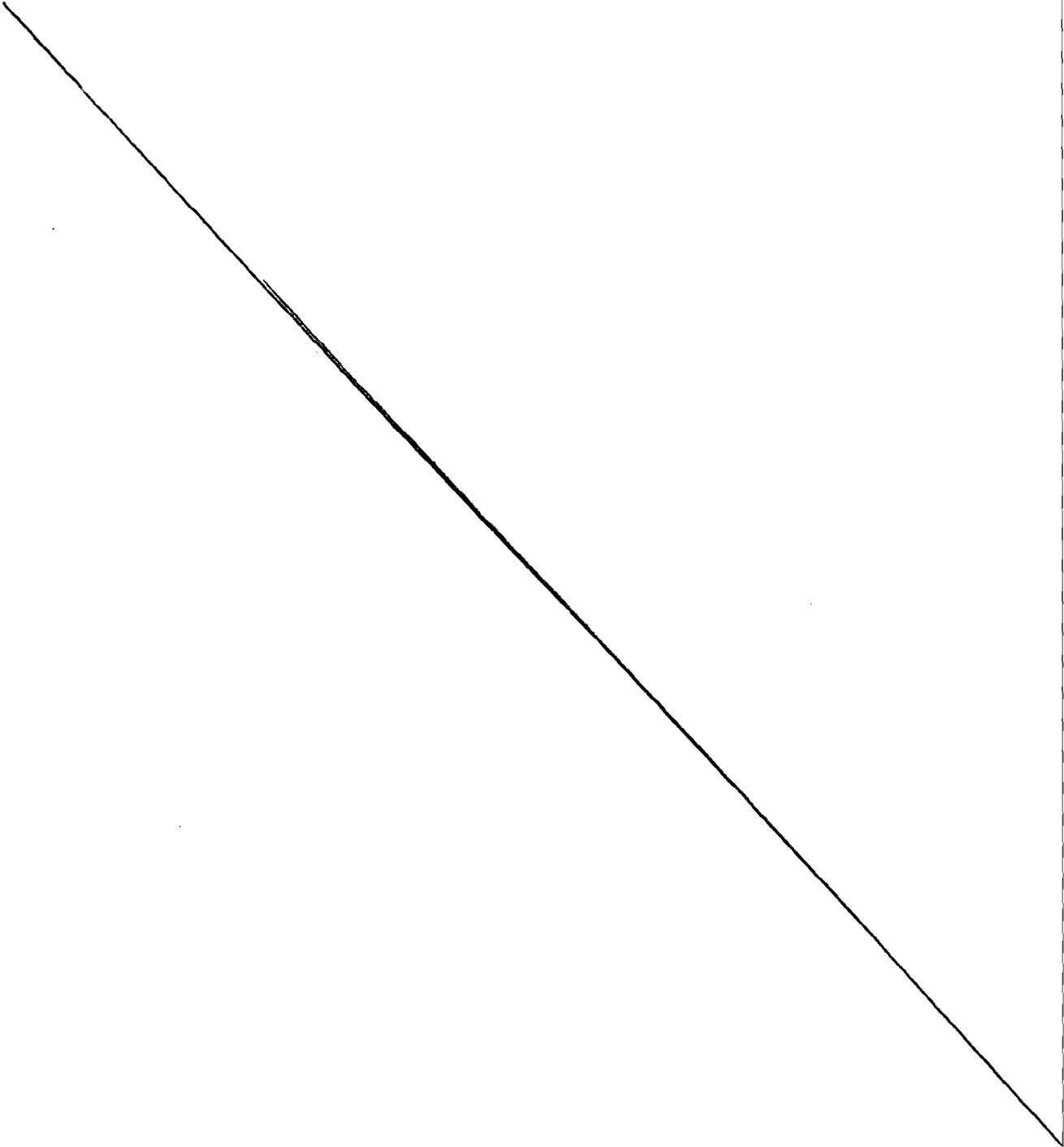
(3)(i) * * *

(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.

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Dated: 11/10/08

cb0811

November 10, 2008



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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