CPSA section 14(a) as applicable, that the product or shipment in question complies with all applicable CPSA rules and all similar rules, bans, standards, and regulations applicable to the product or shipment under any other Act enforced by the Commission.

(b) *Domestic products.* Except as otherwise provided in a specific standard, in the case of a product manufactured in the United States, only the manufacturer must certify in accordance with, and provide the certificate required by, CPSA section 14(a) as applicable, that the product or shipment in question complies with all applicable CPSA rules and all similar rules, bans, standards, and regulations applicable to the product or shipment under any other Act enforced by the Commission.

(c) *Availability of certificates.*

(1) *Imports.* In the case of imports, the certificate required by CPSA section 14(a) must be available to the Commission from the importer as soon as the product or shipment itself is available for inspection in the United States.

(2) *Domestic products.* In the case of domestic products, the certificate required by CPSA section 14(a) must be available to the Commission from the manufacturer prior to introduction of the product or shipment in question into domestic commerce.

§ 1110.9 Form of certificate.

As required by CPSA section 14(g)(2), the information on a hard copy or electronic certificate must be provided in English and may be provided in any other language.

§ 1110.11 Content of certificate.

As required by CPSA sections 14(a) and 14(g), a certificate must contain the following information:

(a) Identification of the product covered by the certificate.

(b) Citation to each CPSC product safety regulation or statutory requirement to which the product is being certified. Specifically, the certificate shall identify separately each applicable consumer product safety rule under the Consumer Product Safety Act and any similar rule, ban, standard or regulation under any other Act enforced by the Commission that is applicable to the product.

(c) Identification of the importer or domestic manufacturer certifying compliance of the product, including the importer or domestic manufacturer's name, full mailing address, and telephone number.

(d) Contact information for the individual maintaining records of test results, including the custodian's name, e-mail address, full mailing address, and telephone number. (CPSC suggests that each issuer maintain test records supporting the certification for at least three years as is currently required by certain consumer product specific CPSC standards, for example at 16 CFR 1508.10 for full-size baby cribs.)

(e) Date (month and year at a minimum) and place (including city and state, country, or administrative region) where the product was manufactured. If the same manufacturer operates more than one location in the same city, the street address of the factory in question should be provided.

(f) Date and place (including city and state, country or administrative region) where the product was tested for compliance with the regulation(s) cited above in subsection (b).

(g) Identification of any third-party laboratory on whose testing the certificate depends, including name, full mailing address and telephone number of the laboratory.

§ 1110.13 Availability of electronic certificate.

(a) CPSA section 14(g)(3) requires that the certificates required by section 14(a) ''accompany'' each product or product shipment and be ''furnished'' to each distributor and retailer of the product in question.

(1) An electronic certificate satisfies the ''accompany'' requirement if the certificate is identified by a unique identifier and can be accessed via a World Wide Web URL or other electronic means, provided the URL or other electronic means and the unique identifier are created in advance and are available, along with access to the electronic certificate itself, to the Commission or to the Customs authorities as soon as the product or shipment itself is available for inspection.

(2) An electronic certificate satisfies the ''furnish'' requirement if the distributor(s) and retailer(s) of the product are provided a reasonable means to access the certificate.

(b) An electronic certificate shall have a means to verify the date of its creation or last modification.

§ 1110.15 Legal responsibility for certificate information.

Any entity or entities may maintain an electronic certificate platform and may enter the requisite data. However, the entity or entities required by CPSA section 14(a) to issue the certificate remain legally responsible for the accuracy and completeness of the certificate information required by statute and its availability in timely fashion.

Dated: November 10, 2008.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E8–27356 Filed 11–13–08; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 November 18, 2008.

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. 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.

* * * * *

(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.

* * * * *

Dated: November 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27254 Filed 11–17–08; 8:45 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4041 and 4042

RIN 1212–AB14

Disclosure of Termination Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is a final rule to implement section 506 of the Pension Protection Act of 2006 (Pub. L. 109–280) which amends sections 4041 and 4042 of ERISA. These amendments require that a plan administrator disclose information it has submitted to PBGC in connection with a distress termination filing, and that a plan administrator or plan sponsor disclose information it has submitted to PBGC in connection with a PBGC-initiated termination. The new provisions also require PBGC to disclose the administrative record in a PBGC-initiated termination. The disclosures must be made to an affected party upon request.

DATES: Effective December 18, 2008. For information about applicability of the amendments made by this rule, see Applicability in the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kenneth Cooper, Assistant General Counsel; or Catherine Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Background

Pension Benefit Guaranty Corporation (''PBGC'') administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 , as amended (''ERISA''), 29 U.S.C. 1301–1461. Sections 4041 and 4042 of ERISA govern the termination of single-employer defined benefit pension plans that are subject to Title IV. A plan administrator may initiate a distress termination by sending a notice of intent to terminate to all affected parties pursuant to section 4041(a)(2). Under section 4042 of ERISA, PBGC may itself initiate proceedings to terminate a pension plan if it determines that certain conditions are present.

Under section 4041(c), a single-employer plan may terminate in a distress termination if PBGC determines that the requirements of section 4041(c)(2)(B) are met. Before PBGC can make this determination, the plan administrator must provide certain information to PBGC pursuant to section 4041(c)(2)(A). Under § 4041.45(c) of PBGC's regulation on Termination of Single Employer Plans, 29 CFR part 4041, PBGC may also require the submission of additional information.

PBGC determines whether a plan meets the criteria for a distress termination or a PBGC-initiated termination through an informal adjudicatory process. If PBGC staff believe that a plan should be terminated, a written recommendation is prepared. With certain exceptions, the recommendation is then reviewed by the Trusteeship Working Group (''TWG''), an interdepartmental body comprised of representatives from PBGC's financial, actuarial, policy, regulatory, and legal departments. If the TWG agrees with the staff recommendation, it forwards its own recommendation concerning the termination to the Director or other designated official (''Deciding Official''). All determinations are documented in a trusteeship decision record.

As part of the informal adjudicatory process, PBGC staff may present or make available to the TWG information and documents that relate to a termination recommendation and, if the TWG recommends termination, to the Deciding Official. This material may include information that PBGC has obtained from the plan sponsor or plan administrator, as well as other information that PBGC has obtained or generated.

For PBGC-initiated terminations, if the Deciding Official approves the termination, PBGC sends a notice to the plan administrator that the determination has been made (''Notice of Determination''). The plan may then be terminated by agreement or PBGC may apply to the appropriate district court for a decree adjudicating that the plan must be terminated.

PPA 2006 Amendments

On August 17, 2006, the President signed into law the Pension Protection Act of 2006, Pub. L. 109–280 (''PPA 2006''). Section 506 of PPA 2006 adds disclosure provisions to both sections 4041 and 4042 of ERISA. These provisions allow an affected party to request information related to a plan termination from the plan administrator in the case of a distress termination under section 4041, and from the plan administrator, plan sponsor, and PBGC in the case of a termination under section 4042. ''Affected party'' is defined in section 4001(a)(21) of ERISA to include each participant in the plan, each beneficiary under the plan, each employee organization representing plan participants, and PBGC.

With respect to distress terminations, the new provisions require that a plan administrator that has filed a Notice of Intent to Terminate must provide to an affected party, upon request, information submitted to PBGC in conjunction with the distress termination. This information must be provided not later than 15 days after receipt of the request. One of the new provisions allows a court to limit disclosure of confidential information to an authorized representative of the