

■ 29. Section 772.1 is amended by revising the definition of “transfer” to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Transfer. A shipment, transmission, or release to any person of items subject to the EAR either within the United States or outside the United States. *In-country transfer/transfer (in-country).* The shipment, transmission, or release of items subject to the EAR from one person to another person that occurs outside the United States within a single foreign country.

Note: This definition of transfer does not apply to § 750.10 or Supplement No. 8 to part 760 of the EAR. The term “transfer” may also be included on licenses issued by BIS. In that regard, the changes that can be made to a BIS license are the non-material changes described in § 750.7(c). Any other change to a BIS license without authorization is a violation of the EAR. See §§ 750.7(c) and 764.2(e).

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Dated: November 10, 2008.

Christopher R. Wall,
Assistant Secretary for Export
Administration.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1110

Certificates of Compliance

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Act (“CPSA”), at section 14(a) as amended by section 102(a) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), Public Law 110–314, requires that, for products manufactured on or after November 12, 2008, manufacturers (including importers) and private labelers of the products certify that the products comply with all applicable CPSA consumer product safety rules and similar rules, bans, standards and regulations under any other laws administered by the Commission by issuing a certificate that accompanies the product and can be furnished to certain parties. The certificate must specify each such rule, ban, standard, or regulation with which the product must comply. In general, the certification must be based on a test of each product

or upon a reasonable testing program. Certificates and certification for certain children’s products must be based on testing by third party laboratories whose accreditation to do so has been accepted by the Commission. The third party testing requirements become effective on a rolling schedule as the Commission issues specific laboratory accreditation requirements. Section 14(a)(4) of the CPSA gives the Commission the authority where there is more than one manufacturer, importer, or private labeler to designate one or more of such entities as the person(s) who shall issue the required certificate and to relieve all others of that responsibility.

The final rule published today limits the parties who must certify to the U.S. importer and, in the case of domestically produced products, the U.S. manufacturer. It also specifies the requirements that an electronic certificate must meet.

DATES: *Effective Date:* This rule is effective November 18, 2008.

FOR FURTHER INFORMATION CONTACT: John “Gib” Mullan, Assistant Executive Director for Compliance and Field Operations, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail: jmullan@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

The Commission is aware that, as a result of the extremely short deadline for complying with the new certificate requirement and its vast expansion over that previously required by section 14(a) (which applied only to products subject to consumer product safety standards under the CPSA) there is substantial confusion over what is required by way of certification.

The Commission has received thousands of inquiries as to how to comply, when to comply, what is required in support of the certification, and what form the certificate must take, as well as hundreds of requests to evaluate an individual product as to what existing and future bans, standards, regulations, or rules might apply to it. Commission staff has been unable to respond to many of these inquiries due to the press of the other very early multiple statutory deadlines imposed on the agency by the CPSIA.

The Commission believes that for the expanded § 14(a) certificate program to be implemented in a fair and orderly way and to produce the benefits intended by Congress, it must be streamlined, at least in its initial phase.

Accordingly, the Commission is exercising its authority under CPSA

section 14(a)(4) by issuing this immediately effective final rule designating the importer as the sole entity that must issue the certificate required by section 14(a) in the case of an imported product.¹ This certificate must be available to the Commission no later than the time when the product or shipment is available for inspection in the United States. The Commission is also designating the domestic manufacturer as the sole entity that must issue the certificate required by section 14(a) in the case of a domestically produced product. This certificate must be available to the Commission upon request before the product or shipment is introduced into domestic commerce.

Section 14(g)(3) of the CPSA as added by section 102(b) of the CPSIA requires that the certificates required by section 14(a) of the CPSA “accompany” each product or shipment of products subject to the certification requirements and be “furnished” to each distributor or retailer of the product. In addition, a copy of the certificate must be “furnished” to the CPSC upon request.

The final rule issued today provides that the requirements of section 14(g)(3) can be satisfied by providing the statutorily required certificate information by electronic means. The means by which the certificate may be provided in electronic form is specified.

This rule is being issued in immediate final form in recognition that the new, broader consumer product certification requirements established by CPSIA go into effect for products manufactured on and after November 12, 2008. The Commission expects that with time CPSIA’s expanded certification requirements will become more routine and it then would consider whether this rule needs to be revised based on actual experience.

The rule issued here is effective upon publication in the **Federal Register**.

II. Pertinent Statutory Provisions

Section 14(a)(1) of the CPSA, as amended by CPSIA, requires that the manufacturer (including the importer) and the private labeler, if any, of a product that is subject to an applicable consumer product safety rule under the CPSA, or similar rule, ban, standard, or regulation under any other Act enforced by the Commission issue a certificate of compliance.² This requirement applies

¹ The Commission voted 2–0 to issue this rule.

² CPSIA section 14(a)(2) imposes additional testing requirements to support certificates of compliance for “children’s products” as defined in section 3(a)(2) of Consumer Product Safety Act. Ninety days after the Commission issues those requirements for a given product or category of

to any such product manufactured on or after November 12, 2008. Section 14(a)(4) provides the Commission with authority to designate by rule one or more of these parties to issue the required certificate and to relieve the other parties enumerated in section 14 from the requirement to furnish certificates.

Sections 14(g)(1) and (2) of the CPSA as added by CPSIA specify the information that must be provided in a certificate.

(1) Identification of issuer and conformity assessment body.—Every certificate required under this section shall identify the manufacturer or private labeler issuing the certificate and any third party conformity assessment body on whose testing the certificate depends. The certificate shall include, at a minimum, the date and place of manufacture, the date and place where the product was tested, each party's name, full mailing address, telephone number, and contact information for the individual responsible for maintaining records of test results.

(2) English language.—Every certificate required under this section shall be legible and all content required by this section shall be in the English language. A certificate may also contain the same content in any other language. Section 14(g)(3) of the CPSA as added by CPSIA specifies the availability of the required certificates.

(3) Availability of certificates.—Every certificate required under this section shall accompany the applicable product or shipment of products covered by the same certificate and a copy of the certificate shall be furnished to each distributor or retailer of the product. Upon request, the manufacturer or private labeler issuing the certificate shall furnish a copy of the certificate to the Commission.

While the new provisions of section 14 do not address electronic certificates in general, new section 14(g)(4) does specifically address electronic filing of certificates for import shipments with CPSC and the Commissioner of Customs.

(4) Electronic filing of certificates for imported products.—In consultation with the Commissioner of Customs, the

Commission may, by rule, provide for the electronic filing of certificates under this section up to 24 hours before arrival of an imported product. Upon request, the manufacturer or private labeler issuing the certificate shall furnish a copy to the Commission and to the Commissioner of Customs.

This rule does not establish the requirements under section 14(g)(4) for pre-arrival electronic filing with the Commissioner of Customs and the Commission of certificates for imported products. Rather it addresses acceptable means for making electronic certificates available to the Commission and to distributors and retailers at this time in compliance with the requirements of CPSA sections 14(a) and (g). If the Commission elects to do so at some future date, it may address the specific issue of electronic filing of certificates for imported products with the Commission and the Commissioner of Customs by subsequent rulemaking.

III. Need for Streamlining Certificate Requirements

Prior to enactment of the CPSIA, the certificate requirement ran to eleven (11) CPSA consumer product safety standards.³ The CPSIA expanded that universe to include all CPSA standards and bans and all similar standards, bans, rules and regulations under any other Act administered by the Commission, including the Federal Hazardous Substances Act, the Flammable Fabrics Act, the Poison Prevention Packaging Act, the Refrigerator Safety Act, the Children's Gasoline Burn Prevention Act, and the Virginia Graeme Baker Pool and Spa Safety Act. Congress provided only ninety days from enactment of the CPSIA for the Commission and the regulated community to address this vastly expanded product certification requirement. As noted above, the Commission has received literally thousands of inquiries as to how to comply, when to comply, what is required in support of the certification, whether and how an electronic certificate might be acceptable, and what form the certificate must take, whether hard copy or electronic.

The Commission is hampered in its overall efforts to implement the CPSIA by the fact it is funded for Fiscal year 2009 by continuing resolution at its

funding level for FY 2008 established prior to enactment of those sweeping new responsibilities. Commission staff has been unable to respond to many inquiries due to the press of the other very early, multiple statutory deadlines imposed on the agency by the CPSIA.

In addition, the staff has been deluged with hundreds and hundreds of requests to evaluate specific individual products and specify what bans, standards, regulations, etc., might apply to them. First, the Commission does not have, or expect to have, sufficient resources to evaluate every one of the products within the scope of the *thousands of types* of products within its jurisdiction in this manner. The CPSC has never "pre-approved" products for compliance with its standards, bans, regulations or rules in this manner in any event. Second, it is the responsibility of the manufacturer of the product as a normal incident of doing business to know what legal requirements of the Commission or otherwise apply to its products.

The Commission is concerned by the apparent confusion among companies about the reach of the general certificate requirements including what rules apply to their products. Manufacturers and retailers have always been required to know which rules apply to their products and to assure that their products comply with those rules. Before it has even gone into effect, the new general certificate requirement has not only focused attention on safety compliance but also has given some companies a cause to be concerned about their ability to comply with the certification program.

While the Commission expects every company to make best efforts to comply promptly with the new general certificate requirements, the Commission's resource limitations under the continuing resolution will force it to focus more on a product's compliance with our safety rules. The certificate is evidence of compliance and therefore it is appropriate to concentrate initially more on the substantive requirements underlying the certificate than on the certificate or the form of the certificate itself. As our resource limitations are fully addressed by Congress, the Commission will then be able to properly focus on all aspects of compliance, *particularly* compliance with the new general certification requirements.

The Commission also recognizes that it still has work to do to clarify aspects of the general certification program and will be working to quickly resolve uncertainties.

products on the rolling schedule specified in section 14(a)(3), the certificate for the product or products in question manufactured after that date must be supported by testing performed by a third party laboratory whose accreditation has been accepted by the Commission absent the Commission's exercise of its authority to extend such a deadline by an additional sixty days in certain instances. The rule set out here is equally applicable to certificates that must be based on third party testing.

³ In most of those standards, the Commission has already addressed which entity must provide certificates under the prior version of CPSA section 14(a). See, e.g., 16 CFR part 1210, etc. Today's rule does not amend those standards in this respect in light of the significant additional certificate information now required by CPSA section 14(a) as amended by CPSIA.

Importers should be aware that after this initial period of adjustment, failure to abide by the general certificate requirement will subject shipments to refusal of admission into the country and potential destruction. The Commission staff is developing Frequently Asked Question (FAQ) lists for posting on the Commission's World Wide Web site as the agency's resources permit to address issues of more general applicability posed by the new CPSIA requirements.

All of the above considerations lead the Commission to the conclusion that at least in the initial implementation phase, the expanded certification program must be streamlined to minimize confusion in the regulated community, to allow for fairness, and to allow the Commission staff to respond appropriately to the most pressing CPSIA implementation challenges. Accordingly, by this rule, the Commission is limiting the certificate requirements of section 14(a) of the CPSA to the importer in the case of products manufactured outside the United States and to the domestic manufacturer in the case of products manufactured in the United States. In the case of imports, the required certificate must be available to the Commission no later than the time when the product or shipment is available for inspection in the United States. In the case of domestic products, the certificate must be available to the Commission prior to introduction of the product or shipment in question into domestic commerce.

IV. Need for Electronic Certificates

Following enactment of CPSIA on August 14th, the Commission has received many comments regarding the urgent need for a means for electronic certificates as an alternative to paper certificates. Importers have noted the extremely difficult task of associating paper certificates with the proper contents of a shipping container that may contain items not subject to the certification requirement and many items that are, but that are subject to varying certification requirements depending on the specific product in question. Similar difficulties have been noted with respect to bulk shipments that are then broken down for shipment to a number of distributors or retailers. Manufacturers of small volume per retailer products have noted the substantial additional complexity and cost if such products must be accompanied by appropriate paper certificates down to the individual retailer level. This latter situation has been identified as extremely

problematic for manufacturers (including importers) and private labelers, that are not associated with major retail chains, but who ship to many independent retailers. Finally many commenters have noted that international and domestic commerce is now largely tracked and otherwise conducted electronically and that a return to paper for some portion of that commerce is a major step backward in facilitating efficient trade. Based on all of the above, the Commission believes that immediately recognizing the suitability of electronic certificates provided they meet the statutory content and availability requirements is appropriate.

V. Electronic Certificates Can "Accompany" Products and Product Shipments and Can Be "Furnished" to Distributors and Retailers

Section 14(g)(3) requires that the certificate "accompany" each product or shipment of products and be "furnished" to each distributor or retailer of the product. The legislative history of section 102(b) of CPSIA is silent as to the intended meaning of the word "accompany." Among other meanings, Webster's defines "accompany" to mean "coexist or occur with."⁴ The Commission believes that a properly designed electronic certificate containing the information prescribed by sections 14(a) and (g) of the CPSA, as applicable, that is uniquely identified to the product or products covered by the certificate is "coexisting" or "occurring with" the product or products in question.

Webster's defines "furnish" as "to supply" or "give."⁵ The Commission believes that an electronic certificate that can be reasonably accessed by distributors and retailers satisfies the requirement of "furnishing" the certificate to distributors and retailers of the product.

VI. Acceptable Form of Electronic Certificate

As noted above in section II. of this preamble, CPSA sections 14(a) and (g) specify the information that must be in a certificate and the form in which it must be available. For purposes of this rule, which limits the requirement to furnish certificates to importers and domestic manufacturers, the applicable portions of those provisions are as follows:

1. Identification of the product covered by the certificate.

2. Citation to each CPSC product safety regulation to which the product is being certified. Specifically, CPSIA requires that the certificate specify 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.

3. Identification of the importer or domestic manufacturer as applicable certifying compliance of the product, including the importer or domestic manufacturer's name, full mailing address, and telephone number.

4. 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 recommends 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.).

5. Date (month and year at a minimum) and place (including city and 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.)

6. Date and place (including city and country or administrative region) where the product was tested for compliance with the regulation(s) cited above.

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

Section 14(g)(2) requires that the foregoing information be available in English. As provided for in CPSIA, the same information also may be provided in any other language.

The Commission expects that the statutory content and language requirements will be met for any certificate, whether issued in electronic or paper form.

The Commission believes that an electronic certificate is properly "accompanying" the product or shipment of the product as required by CPSIA if a certificate meeting the requirements of the rule issued today can reasonably be accessed by information on the product or accompanying the product or shipment, for example a unique identifier that can be accessed via a World Wide Web URL or other electronic means, provided the URL or other electronic means and the certificate and unique identifier are

⁴ Webster's II New Riverside University Dictionary, Houghton Mifflin Company, 1994, at p. 71.

⁵ *Id.* at p. 513.

available to the Commission immediately when the product or shipment itself is available for inspection in the United States. Similarly, if a reasonable means to access the electronic certificate is available to distributor(s) and retailer(s), the Commission believes that the statutory “furnish” requirement is met.

As with paper certificates, for an electronic certificate to “accompany” a shipment, it must be created prior to arrival of the shipment in question into U.S. domestic commerce. The Commission would expect that an electronic certificate would have a means to verify the date of its creation or last modification.

Any entity or entities may maintain the electronic certificate platform(s) and may enter the requisite data. However, the certifying entity or entities remain legally responsible for the accuracy and completeness of the certificate information required by statute and its availability in timely fashion.⁶

VII. Paperwork Reduction Act

This final rule does not impose any information collection requirements. Rather, it restates the express statutory requirements for the content of certificates that appear at sections 14(a) and (g) of the CPSA. Accordingly it is not subject to the Paperwork Reduction Act, 44 U.S.C. sections 3501 through 3520.

VIII. Executive Order 12988

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. This regulation is issued under authority of the CPSA and the CPSIA. The CPSA provision on preemption appears at section 26 thereof. The CPSIA provision on preemption appears at section 231 thereof. Otherwise the preemptive effect of this rule would be determined in an appropriate proceeding in a court of competent jurisdiction.

IX. Environmental Considerations

This final rule falls within the scope of the Commission’s environmental review regulations at 16 CFR 1021.5(c)(2) which provide a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

⁶ It is also self evident that a product subject to an applicable CPSC standard, ban, or regulation is expected to comply therewith, irrespective of the issuance and availability of a certificate.

X. Immediate Effective Date

The Commission is issuing this rule as an immediately effective final rule. Section 553(b) of the Administrative Procedure Act (“APA”), 5 U.S.C. 553, excludes rules from the otherwise applicable notice and comment requirements of the APA, *inter alia*, where the agency for good cause finds that notice and comment are impracticable or contrary to the public interest. Here, the CPSIA statutory deadline for issuance of certificates is November 12, 2008 for products manufactured on or after that date. There is substantial confusion in the regulated community as to the application and implementation of that requirement. Moreover, the Commission’s resources are extremely challenged by the myriad of near term statutory deadlines for implementation of various other CPSIA provisions. Accordingly, the Commission finds that notice and comment on this rule is impracticable and would not be in the public interest.

Section 553(d) of the APA excludes certain final rules from the otherwise applicable APA requirement that the effective date of a rule be at least 30 days after publication of the rule. The pertinent exclusions here are for a rule that relieves a restriction and “as otherwise provided for good cause shown and published with the rule.” In view of the certificate deadline of November 12, 2008 for products subject to the requirement that are manufactured on or after that date, the Commission finds that good cause exists to make this rule effective immediately.

List of Subjects in 16 CFR Part 1110

Consumer protection, labeling.

■ For the reasons stated in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by adding a new part 1110 to read as follows:

PART 1110—CERTIFICATES OF COMPLIANCE

Sec.

1110.1 Purpose and scope.

1110.3 Definitions.

1110.5 Acceptable certificates.

1110.7 Who must certify and provide a certificate.

1110.9 Form of certificate.

1110.11 Contents of certificate.

1110.13 Availability of electronic certificate.

1110.15 Legal responsibility for certificate information.

Authority: Pub. L. No. 110–314, § 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 14.

PART 1110—CERTIFICATES OF COMPLIANCE

§ 1110.1 Purpose and scope.

(a) This part 1110:

(1) Limits the entities required to provide certificates in accordance with section 14(a) of the Consumer Product Safety Act, as amended (CPSA), 15 U.S.C. 2063(a), to importers and U.S. domestic manufacturers;

(2) Specifies the content, form, and availability requirements of the CPSA that must be met for a certificate to satisfy the certificate requirements of section 14(a); and

(3) Specifies means by which an electronic certificate shall meet those requirements.

(b) This part 1110 does not address issues related to type or frequency of testing necessary to satisfy the certification requirements of CPSA section 14(a). It does not address issues related to CPSA section 14(g)(4) concerning advance filing of electronic certificates of compliance with the Commission and/or the Commissioner of Customs.

§ 1110.3 Definitions.

The following definitions apply for purposes of this part 1110.

(a) *Electronic certificate* means, for purposes of this part 1110, a set of information available in, and accessible by, electronic means that sets forth the information required by CPSA section 14(a) and section 14(g) and that meets the availability requirements of CPSA section 14(g)(3).

(b) Unless otherwise stated, the definitions of section 3 of the CPSA and additional definitions in the Consumer Product Safety Improvement Act of 2008 (CPSIA), Pub. L. 110–314, apply for purposes of this part 1110.

§ 1110.5 Acceptable certificates.

A certificate that is in hard copy or electronic form and complies with all applicable requirements of this part 1110 meets the certificate requirements of section 14 of the CPSA. This does not relieve the importer or domestic manufacturer from the underlying statutory requirements concerning the supporting testing and/or other bases to support certification and issuance of certificates.

§ 1110.7 Who must certify and provide a certificate.

(a) *Imports.* Except as otherwise provided in a specific standard, in the case of a product manufactured outside the United States, only the importer 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.

(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.

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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.