

provides manufacturers greater flexibility to meet regulatory requirements, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to protect consumers from those labeling errors that are more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. This rule amends the 1993 final rule by limiting the scope to cut labeling for immediate container labels, individual unit cartons, and multiunit cartons containing immediate containers that are not packaged in individual unit cartons. This rule also increases flexibility for firms selecting special labeling control procedures by adding a provision for the use of any automated technique, including differentiation by size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment. Therefore, this rule is expected to have a positive economic impact on drug manufacturers that would otherwise be subject to the more stringent requirements under current regulations.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- 1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

- 2. Section 211.122 is amended by revising the introductory text of paragraph (g) and by adding paragraph (g)(4) to read as follows:

§ 211.122 Materials examination and usage criteria.

* * * * *

(g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures:

* * * * *

(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

* * * * *

Dated: March 13, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF JUSTICE

28 CFR Parts 35 and 36

[CRT Docket No. 122; AG Order No. 3326–2012]

RIN 1190-AA68

Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities; Swimming Pools

AGENCY: Civil Rights Division, Department of Justice.

ACTION: Final rule.

SUMMARY: By this rule, the Department of Justice is extending the date for

compliance with certain requirements in the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design (2010 Standards) that relate to provision of accessible entry and exit for swimming pools, wading pools, and spas. This final rule, based on a finding of good cause, changes the date for compliance from March 15, 2012, to May 21, 2012 in order to allow additional time to address misunderstandings regarding compliance with these ADA requirements. Some pool owners and operators believed that taking certain steps would always satisfy their obligations under the ADA when in fact those steps would not necessarily result in compliance with the ADA regulations.

DATES: Effective on March 15, 2012, the compliance date for 28 CFR 35.150(b)(1), (b)(2)(ii), and 28 CFR 36.304(d)(2)(iii) for sections 242 and 1009 of the 2010 Standards is delayed to May 21, 2012.

FOR FURTHER INFORMATION CONTACT:

Allison Nichol, Chief, Disability Rights Section, Civil Rights Division, U.S. Department of Justice, at (202) 307-0663 (voice or TTY). This is not a toll-free number. Information may also be obtained from the Department's toll-free ADA Information Line at (800) 514-0301 (voice) or (800) 514-0383 (TTY).

This rule is also available in an accessible format on the ADA Home Page at <http://www.ada.gov>. You may obtain copies of this rule in large print or on computer disk by calling the ADA Information Line listed above.

SUPPLEMENTARY INFORMATION: The Department of Justice published its revised final regulations implementing the Americans with Disabilities Act (ADA) for title II (State and local government services) and title III (public accommodations and commercial facilities) on September 15, 2010. *See* 75 FR 56163. The revised ADA rules were the result of a six-year process to update the Department's regulations. As part of this process, the Department sought extensive public comment, issuing an Advance Notice of Proposed Rulemaking (ANPRM) on September 30, 2004, 69 FR 58768, and two Notices of Proposed Rulemaking (NPRM) on June 17, 2008, 73 FR 34466 (title II), and 73 FR 34508 (title III). The Department also held a public hearing on the NPRMs and received over 4,435 written public comments. On September 15, 2010, the Department published a final rule revising the regulations implementing titles II and III of the ADA. As part of this revision, the Department adopted the 2010 ADA Standards for Accessible

Design (“2010 Standards”), which are based in large part on the 2004 ADA Accessibility Guidelines adopted by the United States Access Board in 2004. *See* 69 FR 44083 (July 23, 2004). With limited exception, the Department’s revised regulations went into effect on March 15, 2011.

With a compliance deadline of March 15, 2012, the 2010 Standards set minimum scoping and technical requirements for accessible entry and exit for new construction and alteration of swimming pools, wading pools, and spas (collectively, “pools”). In addition, the title III regulation provides that as of March 15, 2012, public accommodations’ barrier removal efforts must comply with the 2010 Standards to the extent readily achievable, including with respect to barriers to accessing pools. 28 CFR 36.304 (d)(2)(iii). The title II regulation provides that the 2010 Standards apply where public entities choose to meet their title II ADA program access obligations by making structural changes to their pools. 28 CFR 35.150(b)(1), (b)(2)(ii).

Regulatory Certifications

Administrative Procedure Act

The Department of Justice finds that good cause exists for adopting this rule as a final rule with an immediate effective date because proceeding via ordinary Administrative Procedure Act process would be impracticable and contrary to the public interest. *See* 5 U.S.C. 553(b). The Department promulgated a Final Rule on September 15, 2010 (the 2010 Final Rule), adopting the 2010 ADA Standards for Accessible Design and implementing ADA title II requirements for program accessibility and the title III requirements for readily achievable barrier removal as applied to existing swimming programs and swimming pools. As the March 15, 2012, date for compliance approached, the Department received a large number of inquiries regarding the obligations of owners and operators of existing pools under the 2010 Final Rule. On January 31, 2012, the Department of Justice Civil Rights Division published a technical assistance document entitled “ADA 2010 Revised Requirements: Accessible Pools—Means of Entry and Exit” (the “TA Document”). The Civil Rights Division issued the TA document to educate public entities and public accommodations about their obligations under the ADA regulations as revised by the 2010 Final Rule.

Both the inquiries received by the Department prior to the TA Document’s publication and the pool owners and operators’ response to the TA Document

reveal that there were misunderstandings among a substantial number of pool owners and operators concerning the obligations imposed by the ADA as implemented in the 2010 Final Rule as to their obligations with respect to existing pools and their options with respect to the provision of pool lifts. Some pool owners and operators believed that taking certain steps would always satisfy their obligations when in fact those steps would not necessarily result in compliance with the ADA regulations. Recognizing that pool owners and operators face challenges in correcting their misunderstandings and determining appropriate compliance when faced with what is now an immediate compliance date, the Department determined that it would be impracticable and contrary to the public interest to retain the existing compliance date, and that a brief 60-day extension of that date is necessary to provide an opportunity for pool owners and operators to assess their obligations under the Final Rule and determine how best to comply. Further, the Department is contemporaneously issuing a Notice of Proposed Rulemaking seeking public comment on whether an even longer period of time to allow pool owners and operators to meet their compliance obligations would be appropriate. Accordingly, this 60-day extension of the compliance date is intended to avoid economic effects and disruption of the existing status quo while enabling public comment and meaningful review of those comments on the question of whether a longer extension of the compliance date is warranted. Thus, the government concludes that the requisite good cause for issuance of this final rule exists, and the requirements for notice and comment are not applicable to this brief extension of the compliance date set forth in the 2010 Final Rule. 5 U.S.C. 553(b).

Additionally, this rule is effective immediately on date of display for public inspection in the **Federal Register**. Section 553(d) of the Administrative Procedures Act requires 30-days notice before the effective date of a final rule. However, section 553(d)(1) allows an exception to the 30-day notice where a rule relieves a restriction. Because this final rule relieves a restriction, in the form of an existing date for compliance with a regulatory requirement, the Department invokes section 553(d)(1) to allow an immediate effective date.

Executive Order 12866—Regulatory Planning and Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review” section 1(b), Principles of Regulation. The Department of Justice has determined that this rule is a “significant regulatory action” under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988—Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. § 605(b)), has reviewed this regulation, and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This rule merely extends for 60 days the compliance date of the specified provisions of the title II and title III ADA rules to avoid economic effects and disruption of the existing status quo while enabling public comment and meaningful review of those comments on the question of whether a longer extension of the compliance date is warranted.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-

based companies in domestic and export markets.

Unfunded Mandates Reform Act of 1995

Section 4(2) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1503(2), excludes from coverage under that Act any proposed or final Federal regulation that “establishes or enforces any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability.” Accordingly, this rulemaking is not subject to the provisions of the Unfunded Mandates Reform Act.

Paperwork Reduction Act of 1995

This rule does not contain any information collection requirements that require approval by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Dated: March 15, 2012.

Eric H. Holder, Jr.,
Attorney General.

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Parts 321 and 330

United States Savings Bonds and Notes; Payments

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: Treasury is changing the procedures for financial institutions to transmit and receive settlement for redeemed definitive (paper) savings securities (savings bonds and savings notes) from the EZ Clear system to an image-based securities process through the Federal Reserve. By changing the procedures, Treasury will reduce costs and provide for a more efficient method of processing savings securities through the Federal Reserve. Treasury is making discretionary the payment of fees to paying agents for the processing of redeemed definitive savings securities. Treasury will have the flexibility to adjust paying agent fees and significantly reduce program costs.

DATES: *Effective date:* April 11, 2012.

ADDRESSES: You can download this Final Rule at the following Internet addresses: <<http://www.publicdebt.treas.gov>>, <<http://www.gpo.gov>>, or <<http://www.regulations.gov>>.

FOR FURTHER INFORMATION CONTACT: D. Michael Linder, Director, Division of Program Administration, Office of Retail Securities, Bureau of the Public Debt, at (304) 480-6319 or <mike.linder@bpd.treas.gov>.

Ann Fowler, Attorney-Adviser, Brian Metz, Attorney-Adviser, Dean Adams, Assistant Chief Counsel, Edward Gronseth, Deputy Chief Counsel, Office of the Chief Counsel, Bureau of the Public Debt, at (304) 480-8692 or <dean.adams@bpd.treas.gov>.

SUPPLEMENTARY INFORMATION: United States savings securities are non-marketable Treasury securities. Generally, definitive savings securities are redeemed by banks and other financial institutions that are authorized by Treasury as paying agents to redeem eligible savings securities for cash and process those securities in accordance with Treasury regulations and instructions.

Beginning October 1, 1988, Treasury permitted paying agents to transmit and receive settlement for redeemed definitive savings securities through the EZ CLEAR system, under which the securities are manually sorted and mailed to the appropriate Federal Reserve Bank or Branch. Service fees for redeemed definitive savings securities presented through EZ CLEAR are paid to the institution presenting the securities to a Federal Reserve Bank.

Effective April 11, 2012, financial institutions will begin to transition the submission of redeemed definitive savings securities from the EZ CLEAR process to an existing image-based securities process through the Federal Reserve. Use of this existing image-based securities process will enable paying agents to image redeemed definitive savings securities in the same manner as they do for checks and electronically transmit the images to a Federal Reserve Processing Site for payment. The Federal Reserve will provide specific details on the use of the image-based securities process while the Bureau of the Public Debt will provide other detailed instructions to paying agents via its Web site at www.treasurydirect.gov and other established means of communication such as FedFlash and FedFocus. The new procedures will enable financial institutions to eliminate the manual sorting of redeemed definitive savings securities and mailing them to a Federal Reserve Bank for clearing. This will simplify and modernize the processing of redeemed definitive savings securities for paying agents.

Treasury will be using a more streamlined, efficient, and cost-effective

method for redeeming and processing definitive savings securities through a Federal Reserve Processing Site to which the paying agent is instructed to transmit images of redeemed definitive savings securities for payment. The Federal Reserve Bank of Minneapolis will continue to provide fiscal services as the designated Treasury Retail Securities Site.

The new procedures eliminate exception processing for paying agents and greatly reduce their handling costs. Accordingly, Treasury is making the payment of paying agent fees discretionary, which will allow Treasury the flexibility to adjust paying agent fees and significantly reduce Treasury's program costs. Treasury anticipates that most agents will continue redeeming definitive savings securities as a service to their customers.

Procedural Requirements

Executive Order 12866. This rule is not a significant regulatory action pursuant to Executive Order 12866.

Administrative Procedure Act (APA). Because this rule relates to United States securities, which are contracts between Treasury and the owner of the security, this rule falls within the contract exception to the APA, 5 U.S.C. 553(a)(2). As a result, the notice, public comment, and delayed effective date provisions of the APA are inapplicable to this rule.

Regulatory Flexibility Act. The provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, do not apply to this rule because, pursuant to 5 U.S.C. 553(a)(2), it is not required to be issued with notice and opportunity for public comment.

Paperwork Reduction Act (PRA). We ask for no collections of information in this final rule. Therefore, the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, does not apply.

Congressional Review Act (CRA). This rule is not a major rule pursuant to the CRA, 5 U.S.C. 801 *et seq.*, because it is a minor amendment that is expected to decrease costs for taxpayers; therefore, this rule is not expected to lead to any of the results listed in 5 U.S.C. 804(2). This rule will take effect April 11, 2012, after we submit a copy of it to Congress and the Comptroller General.

List of Subjects

31 CFR Part 321

Banks and banking, Federal Reserve System, Government Securities.

31 CFR Part 330

Banks and banking, Federal Reserve System, Government Securities.