Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1220

[No. LS–05–07]

Soybean Promotion and Research Program; Section 610 Review

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of review and request for comments.

SUMMARY: This action announces the Agricultural Marketing Service's (AMS) review of the Soybean Promotion and Research Program (conducted under the Soybean Promotion and Research Order), under the criteria contained in section 610 of the Regulatory Flexibility Act (RFA).

DATES: Written comments on this notice must be received by January 31, 2006.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice of review. Comments must be sent to Kenneth R. Payne, Chief, Marketing Programs, Livestock and Seed Program, AMS, USDA, Room 2638–S, STOP 0251, 1400 Independence Avenue, SW., Washington, DC 20250–0251; Fax: (202) 720–1125; or via e-mail at *soybeancomments@usda.gov*. All comments should reference the docket number, the date, and the page number of this issue of the **Federal Register**. Comments will be available for public inspection via the Internet at *http://www.ams.usda.gov/lsg/mpb/rp-soy.htm* or during regular business hours.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Payne, Chief; Marketing Programs Branch; Livestock and Seed Program, AMS, USDA; STOP–0251; 1400 Independence Avenue, SW., Washington, DC 20250–0251. Telephone number 202/720–1115.

SUPPLEMENTARY INFORMATION: The Soybean Promotion and Research Order (Order) (7 CFR 1220) is authorized under the Soybean Promotion, Research, and Consumer Information Act (Act) (7 U.S.C. 6301 *et seq.*). This program is a national producer program for soybean and soybean product promotion, research, consumer information, and industry information as part of a comprehensive strategy to strengthen the soybean industry's position in the marketplace by maintaining and expanding existing domestic and foreign markets and uses for soybeans and soybean products, and to develop new markets and uses for soybean and soybean products. Soybean producers fund this program through a mandatory assessment of one-half of one percent (0.5 percent) of the net market price per bushel on soybeans marketed. Assessments collected under this program are used for promotion, research, consumer information, and industry information.

The national program is administered by the United Soybean Board (Board), which has 64 producer members. Board members serve 3-year terms and represent one of 30 geographic units. The Order became effective on July 9, 1991.

AMS published in the **Federal Register** (64 FR 8014; February 18, 1999), its plan to review certain regulations.

On January 4, 2002, AMS published in the **Federal Register** (67 FR 525), an update to its plan to review regulations, including the Soybean Promotion and Research Program (conducted under the Soybean Promotion and Research Order), under criteria contained in section 610 of the Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612). Because many AMS regulations impact small entities, AMS decided, as a matter of policy, to review certain regulations which, although they may not meet the threshold requirement under section 610 of the RFA, warrant review. Accordingly, this notice and request for comments is made for the Order.

The purpose of the review is to determine whether the Order should be continued without change, amended, or rescinded (consistent with the objectives of the Act) to minimize the impacts on small entities. AMS will consider the continued need for the Order; the nature of complaints or comments received from the public concerning the Order; the complexity of the Order; the extent to which the promotion Order overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local government rules; and the length of time since the Order has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the Order.

Written comments, views, opinions, and other information regarding the Order's impact on small businesses are invited.

Authority: 7 U.S.C. 6301–6311.

Dated: November 28, 2005.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E5–6786 Filed 12–1–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 2005N–0355]

RIN 0910–AF20

Revocation of Status of Specific Products; Group A Streptococcus; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove the regulation applicable to the status of specific products; Group A streptococcus. FDA is proposing to remove the regulation because the existing requirement for Group A streptococcus organisms and derivatives is both obsolete and a perceived impediment to the development of Group A streptococcus vaccines. The regulation was written to apply to a group of products that are no longer on the market. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. We are taking this

action because the proposed change is noncontroversial, and we do not anticipate any significant adverse comments. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: Submit written or electronic comments on or before February 15, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0335 and/or RIN number 0910–AF20, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number or regulatory information number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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:

I. Background

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. We are publishing the direct final rule because the rule is noncontroversial, and we do not anticipate that it will receive any significant adverse comments.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subjects of a significant adverse comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on June 2, 2006. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

Section 610.19 *Status of specific products; Group A streptococcus* (21 CFR 610.19), was published in the **Federal Register** of January 5, 1979 (44 FR 1544). FDA issued that regulation after reviewing and considering the findings of the independent advisory Panel on Review of Bacterial Vaccines and Bacterial Antigens with ''No U.S. Standard of Potency'' (the Panel). The preamble to the proposed rule for § 610.19, which was published in the **Federal Register** of November 8, 1977 (42 FR 58266), contained the findings of the Panel, including the Panel's specific findings about then-licensed products that contained Group A streptococcus (42 FR 58266 at 58277 to 58278). The regulation was a part of the Panel's review of the safety, effectiveness, and labeling of biological products licensed before July 1, 1972. In 1972, the regulatory authority of these biological products was transferred from the National Institutes of Health (NIH) to FDA. The Panel reviewed those licensed biological bacterial products that were labeled, ''No U.S. Standard of Potency.'' (There was a separate review for the ''Bacterial Vaccines and Toxoids with Standards of Potency.'') Products considered by the Panel included primarily mixtures of bacterial preparations, e.g., Mixed Vaccine Respiratory, which was described as containing chemically killed organisms consisting of *Streptococcus* (*pyrogenes*, *viridans*, and *nonhemolytic*), *Staphylococcus* (*aureus* and *albus*), *Diplococcus pneumoniae*, *Neiserria catarrhalis*, *Klebsiella pneumoniae*, and *Haemophilus influenzae* manufactured by Hollister-Stier, Division of Cutter Laboratories (42 FR 58266 at 58268). Many of the products considered by the Panel were indicated as treatments for diverse ailments such as colds, asthma, arthritis, and uveitis (42 FR 58266 at 58270).

The Panel report listed a number of major concerns with this group of products (''No U.S. Standard of Potency'') (42 FR 58266 at 58269). One of the major concerns was that no defined standards of potency existed for any of the products, so it was not possible to establish that the microbial factors manufacturers claimed to be present in the products were indeed

there or in what concentration (42 FR 58266 at 58270). Many of these products were developed years before specific etiologic agents were associated with the cause of specific diseases. Moreover, the labeled indications for these products were for diseases of obscure etiology (Id.). Manufacturers could provide to the Panel neither clinical data to support the safety or efficacy of the products, nor any justification for using the products as described other than uncontrolled and unconfirmed clinical impressions (Id.). Additional safety questions arose from the fact that the products were administered repeatedly over extended periods of time with no evidence of systematic followup for the types of adverse effects that might be associated with repeated inoculations (Id.). The Panel stated in their report, that in view of what was known from laboratory studies about potential risks associated with repeated inoculations of foreign substances, they had reservations about the long-term safety of this group of products (42 FR 58266 at 58270 through 58271). In fact, the Panel did not classify any of these products into category I (those biological products determined to be safe, effective, and not misbranded) (42 FR 58266 at 58315).

In the Panel report, the section specifically concerning Group A streptococcal vaccines describes the history, dating back to the 1930s, of major attempts to immunize humans with hemolytic streptococci (42 FR 58266 at 58277). These early studies demonstrated severe systemic toxicities (Id.). One study (Ref. 1) described the occurrence of acute rheumatic fever in siblings of rheumatic fever patients following vaccination with a partially purified preparation (Id.). In addition, immunological cross-reactivity between streptococcal cell wall protein and mammalian myocardium was demonstrated in vitro (Id.) (Ref. 2). However, the Panel report differentiated between the licensed products under review and highly purified preparations, which were at the research stage. The Panel report stated that the safety profile for a highly purified preparation was quite different, noting that no anti-heart reactive antibody has been observed in the post immunization sera of infants or adults receiving the purified preparation (Id.) (Ref. 3). The Panel concluded, based on demonstrated safety concerns, that the uncontrolled use of the Group A streptococcal antigens in bacterial vaccines with ''No U.S. Standard of Potency'' represented unacceptable risks (42 FR 58266 at 58278). In fact, the Panel stated:

> In view of the carefully conducted controlled studies currently under way with purified chemically defined antigenic preparations, one finds it difficult to justify the use of uncontrolled, poorly defined preparations presumed to contain antigens that have been demonstrated in earlier studies to produce local and systemic reactions. The hypothetical and theoretical objections stemming from laboratory studies linking mammalian and streptococcal antigens have been given serious consideration in the design and conduct of present studies treating humans with the newer purified streptococcal antigens. (42 FR 58266 at 58277). In contrast to the uncontrolled, poorly defined preparations, the Panel made clear at the time that they were not condemning the use of purified or characterized streptococcal antigens (Id.). Further, FDA reviews each biological product and determines whether the risk-benefit relationship is acceptable for the stage of investigation and for licensure (see 21 CFR parts 312 and 601). This review is performed under the authority of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act (see 21 U.S.C. 355(i); 42 U.S.C. 262(a)(3) and (a)(2)(A)). FDA's review is adequate to assess the safety, purity, and potency of products that companies seek to license, and to ensure that human subjects in clinical trials of investigational products are not exposed to unreasonable and significant risk of illness or injury.

Therefore, FDA concludes that § 610.19, which was codified following the Panel report, was meant to apply only to those bacterial vaccines which the Panel had under their review—licensed but poorly characterized products labeled ''No U.S. Standard of Potency''—and not to more characterized preparations under investigation then or now. Because there are no bacterial mixtures with ''No U.S. Standard of Potency'' containing Group A streptococcal antigens licensed at this time, and current manufacturing technology allows for characterization and purification of Group A streptococcal products, this regulation is obsolete. Although it was never intended to apply to the development of Group A streptococcal vaccines that had adequate testing, FDA has determined that it has been perceived to cover these products as well, and therefore should be removed.

II. Highlights of the Proposed Rule

We are proposing to remove § 610.19 because the existing requirement is obsolete and perceived to be impeding the development of Group A streptococcal vaccines using purified or characterized streptococcal antigens. The regulation is obsolete because it was written to apply to a group of products that are no longer on the market. Certain parties interested in developing new Group A streptococcal vaccines perceive the regulation as an impediment, voiced during public meetings and workshops, e.g., the Group A streptococcus workshop sponsored by the National Institute of Allergy and Infectious Diseases, NIH, held in Bethesda, MD on March 29 and 30, 2004. Group A streptococci are responsible for significant morbidity and mortality worldwide, including rheumatic fever and glomerulonephritis, as well as pharyngitis, impetigo, and other clinical manifestations. Therefore, a vaccine to prevent diseases caused by this organism would have a public health benefit. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection.

III. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act of 1995

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule is removing a regulation, it would not result in any increased burden or costs on small entities. Therefore, the agency certifies that the proposed 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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined, under 21 CFR 25.31(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.

C. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IV. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Massell, B.F., L.H. Honikman, and J. Amezcua, ''Rheumatic Fever Following Streptococcal Vaccination. Report of Three Cases,'' *Journal of the American Medical Association*, 207(6): 1115–1119, 1969.

2. Kaplan, M.H. and M. Meyeserian, ''An Immunological Cross-Reaction Between Group A Streptococcal Cells and Human Heart Tissue,'' *Lancet*, 1:706–710, 1962.

3. Fox, E.N., L.M. Pachman, M.K. Wittner, and A. Dorfman, ''Primary Immunization of Infants and Children with Group A Streptococcal M Protein,'' *Journal of Infectious Diseases*, 120:598–604, 1969.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated by the Commissioner of Food and Drugs, it is proposed that 21 CFR part 610 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.19 [Removed]

2. Remove § 610.19.

Dated: November 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23545 Filed 12–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124988–05]

RIN 1545–BE72

Updated Mortality Tables for Determining Current Liability

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations under section 412(l)(7)(C)(ii) of the Internal Revenue Code (Code) and section 302(d)(7)(C)(ii) of the Employee Retirement Income Security Act of 1974 (ERISA) (Pub. L. 93–406, 88 Stat. 829). These regulations provide the public with guidance regarding mortality tables to be used in determining current liability under section 412(l)(7) of the Code and section 302(d)(7) of ERISA. These regulations affect plan sponsors and administrators, and participants in and beneficiaries of, certain retirement plans.

DATES: Written or electronic comments and requests to speak and outlines of topics to be discussed at the public hearing scheduled for April 19, 2006, at 10 a.m., must be received by March 29, 2006.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–124988–05), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–124988–05), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically directly to the IRS Internet site at *http://www.irs.gov/regs.* The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Bruce Perlin or Linda Marshall at (202) 622–6090 (not a toll-free number); concerning submissions and the hearing and/or to be placed on the building access list to attend the hearing, Treena Garrett at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 412 of the Internal Revenue Code provides minimum funding requirements with respect to certain defined benefit pension plans.[1] Section 412(l) provides additional funding requirements for certain of these plans, based in part on a plan's unfunded current liability, as defined in section 412(l)(8).

Pursuant to section 412(c)(6), if the otherwise applicable minimum funding requirement exceeds the plan's full funding limitation (defined in section 412(c)(7) as the excess of a specified measure of plan liability over the plan assets), then the minimum funding for

[1] Section 302 of ERISA sets forth funding rules that are parallel to those in section 412 of the Code. Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713) and section 302 of ERISA, the Secretary of the Treasury has interpretive jurisdiction over the subject matter addressed in these proposed regulations for ERISA, as well as the Code. Thus, these proposed Treasury regulations issued under section 412 of the Code apply as well for purposes of section 302 of ERISA.