

adverse economic impacts, the Commission will, as appropriate, also follow its Small Business Enforcement Policy set forth at § 1020.5.

(b) *Other factors as appropriate.* In determining the amount of any civil penalty to be sought for a violation of the CPSA, FHSA, or FFA, the Commission may consider, as appropriate, such other factors in addition to those listed in the statutes. Both the Commission and a person may raise any factors they believe are relevant in determining an appropriate penalty amount. A person will be notified of any factors beyond those enumerated in the statutes that the Commission relies on as aggravating factors for purposes of determining a civil penalty amount. Additional factors that may be considered in a case include, but are not limited to, the following:

(1) *Safety/compliance program and/or system relating to a violation.* The Commission may consider, when a safety/compliance program and/or system as established is relevant to a violation, whether a person had at the time of the violation a reasonable and effective program or system for collecting and analyzing information related to safety issues. Examples of such information would include incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns. The Commission may also consider whether a person conducted adequate and relevant premarket and production testing of the product at issue; had a program in place for continued compliance with all relevant mandatory and voluntary safety standards; and other factors as the Commission deems appropriate. The burden to present clear, reliable, relevant, and sufficient evidence of such program, system, or testing rests on the person seeking consideration of this factor.

(2) *History of noncompliance.* The Commission may consider whether or not a person's history of noncompliance with the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder, should increase the amount of the penalty. A person's history of noncompliance may be indicated by, for example, multiple violations of one or more laws or regulations that the CPSC enforces, including repeated violations of the same law or regulation. History of noncompliance may include the number of previous violations or how recently a previous violation occurred.

(3) *Economic gain from noncompliance.* The Commission may consider whether a person benefitted

economically from a failure to comply, including a delay in complying, with the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder.

(4) *Failure to respond in a timely and complete fashion to the Commission's requests for information or remedial action.* The Commission may consider whether a person's failure to respond in a timely and complete fashion to requests from the Commission for information or for remedial action should increase a penalty. This factor is intended to address a person's dilatory and egregious conduct in responding to written requests for information or remedial action sought by the Commission, but not to impede any person's lawful rights.

#### **§ 1119.5 Enforcement notification.**

A person will be informed in writing if it is believed that the person has violated the law and if the Commission intends to seek a civil penalty. Any person who receives such a writing will have an opportunity to submit evidence and arguments that it should not pay a penalty or should not pay a penalty in the amount sought by the Commission.

Dated: March 24, 2010.

**Todd A. Stevenson,**  
*Secretary, Consumer Product Safety Commission.*

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## **DEPARTMENT OF LABOR**

### **Employment and Training Administration**

#### **20 CFR Part 655**

#### **Temporary Employment of Foreign Workers in the United States**

##### *CFR Correction*

In Title 20 of the Code of Federal Regulations, Part 500 to End, revised as of April 1, 2009, on page 466, remove § 655.0 and correctly reinstate it to read as follows:

#### **§ 655.0 Scope and purpose of part.**

(a) *Subparts A, B, and C—(1) General.* Subparts A, B, and C of this part set out the procedures adopted by the Secretary to secure information sufficient to make factual determinations of: (i) Whether U.S. workers are available to perform temporary employment in the United States, for which an employer desires to employ nonimmigrant foreign workers, and (ii) whether the employment of aliens for such temporary work will adversely affect the wages or working

conditions of similarly employed U.S. workers. These factual determinations (or a determination that there are not sufficient facts to make one or both of these determinations) are required to carry out the policies of the Immigration and Nationality Act (INA), that a nonimmigrant alien worker not be admitted to fill a particular temporary job opportunity unless no qualified U.S. worker is available to fill the job opportunity, and unless the employment of the foreign worker in the job opportunity will not adversely affect the wages or working conditions of similarly employed U.S. workers.

(2) *The Secretary's determinations.* Before any factual determination can be made concerning the availability of U.S. workers to perform particular job opportunities, two steps must be taken. First, the minimum level of wages, terms, benefits, and conditions for the particular job opportunities, below which similarly employed U.S. workers would be adversely affected, must be established. (The regulations in this part establish such minimum levels for wages, terms, benefits, and conditions of employment.) Second, the wages, terms, benefits, and conditions offered and afforded to the aliens must be compared to the established minimum levels. If it is concluded that adverse effect would result, the ultimate determination of availability within the meaning of the INA cannot be made since U.S. workers cannot be expected to accept employment under conditions below the established minimum levels. *Florida Sugar Cane League, Inc. v. Usery*, 531 F. 2d 299 (5th Cir. 1976).

Once a determination of no adverse effect has been made, the availability of U.S. workers can be tested only if U.S. workers are actively recruited through the offer of wages, terms, benefits, and conditions at least at the minimum level or the level offered to the aliens, whichever is higher. The regulations in this part set forth requirements for recruiting U.S. workers in accordance with this principle.

(3) *Construction.* This part and its subparts shall be construed to effectuate the purpose of the INA that U.S. workers rather than aliens be employed wherever possible. *Elton Orchards, Inc. v. Brennan*, 508 F. 2d 493, 500 (1st Cir. 1974); *Flecha v. Quiros*, 567 F. 2d 1154 (1st Cir. 1977). Where temporary alien workers are admitted, the terms and conditions of their employment must not result in a lowering of the terms and conditions of domestic workers similarly employed, *Williams v. Usery*, 531 F. 2d 305 (5th Cir. 1976); *Florida Sugar Cane League, Inc. v. Usery*, 531 F.

2d 299 (5th Cir. 1976), and the job benefits extended to any U.S. workers shall be at least those extended to the alien workers.

(b) *Subparts D and E.* Subparts D and E of this part set forth the process by which health care facilities can file attestations with the Department of Labor for the purpose of employing or otherwise using nonimmigrant registered nurses under H-1A visas.

(c) *Subparts F and G.* Subparts F and G of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing alien crewmembers in longshore work under D-visas and enforcement provisions relating thereto.

(d) *Subparts H and I of this part.* Subpart H of this part sets forth the process by which employers can file labor condition applications (LCAs) with, and the requirements for obtaining approval from, the Department of Labor to temporarily employ the following three categories of nonimmigrants in the United States: (1) H-1B visas for temporary employment in specialty occupations or as fashion models of distinguished merit and ability; (2) H-1B1 visas for temporary employment in specialty occupations of nonimmigrant professionals from countries with which the United States has entered into certain agreements identified in section 214(g)(8)(A) of the INA; and (3) E-3 visas for nationals of the Commonwealth of Australia for temporary employment in specialty occupations. Subpart I of this part establishes the enforcement provisions that apply to the H-1B, H-1B1, and E-3 visa programs.

(e) *Subparts J and K of this part.* Subparts J and K of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing nonimmigrant alien students on F-visas in off-campus employment and enforcement provisions relating thereto.

[43 FR 10312, Mar. 10, 1978, as amended at 52 FR 20507, June 1, 1987; 55 FR 50510, Dec. 6, 1990; 56 FR 24667, May 30, 1991; 56 FR 54738, Oct. 22, 1991; 56 FR 56875, Nov. 6, 1991; 57 FR 1337, Jan. 13, 1992; 57 FR 40989, Sept. 8, 1992; 69 FR 68226, Nov. 23, 2004; 73 FR 19947, Apr. 11, 2008]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

[Docket No. FDA-2003-N-0446] (formerly Docket No. 2003N-0324)

#### New Animal Drugs; Removal of Obsolete and Redundant Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is removing portions of a regulation that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofurans, and sulfonamide drugs administered in animal feed as these regulations have been determined to be obsolete or redundant. The portions of the regulation being removed are provisions listing certain feed use combinations for oxytetracycline and neomycin in the tables contained in that regulation. This rule does not finalize the provisions of the proposed rule regarding removing the remainder of the regulation.

**DATES:** This rule is effective April 30, 2010.

**FOR FURTHER INFORMATION CONTACT:** William T. Flynn, Center for Veterinary Medicine (HFV-50), 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of August 8, 2003 (68 FR 47272), FDA published a notice of proposed rulemaking to remove 21 CFR 558.15 *Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals* (§ 558.15 (21 CFR 558.15)) on the grounds that these regulations were obsolete or redundant. The proposed rule explained the nature and purpose of § 558.15, and noted that most of the products and use combinations subject to the listings in that section had approvals that were already codified in part 558, subpart B (21 CFR part 558, subpart B).

In the same issue of the *Federal Register* as the proposed rule, FDA's Center for Veterinary Medicine (CVM) published a Notice of Opportunity for Hearing (NOOH), which announced CVM's findings of effectiveness for nine products and use combinations that were listed in § 558.15, but which were subject to the Drug Efficacy Study Implementation (DESI) program (68 FR

47332). CVM proposed to withdraw the new animal drug applications (NADAs) for those nine products and use combinations lacking substantial evidence of effectiveness, following an opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency provided an opportunity for hearing.

FDA received hearing requests regarding two products owned by Pennfield Oil Co. (Pennfield). One is a bacitracin methylene disalicylate (BMD) Type A medicated article, NADA 141-137, that is listed in the table in § 558.15(g)(1). This listing is under Fermenta Animal Health Co., which is a predecessor in interest to Pennfield. The other is a two-way, fixed-combination Type A medicated article containing oxytetracycline and neomycin sulfate, NADA 138-939, that is listed in the table in § 558.15(g)(2).

The agency received only one set of comments on the 2003 proposed rule, from Pennfield. The comment objected to the removal of § 558.15 until the issues in the NOOH are addressed. It argued that the BMD listing in § 558.15 provides evidence of Pennfield's approval, and that removal of that section, without updating the BMD listing in part 558, subpart B, would result in a lack of recognition in the regulations of the approval that Pennfield currently has.

In 2006, FDA finalized portions of the 2003 proposed rule. In that final rule (71 FR 16219, March 31, 2006), FDA removed from the tables in § 558.15(g) products and use combinations that were not approved, and products and use combinations whose approval was reflected in part 558, subpart B. FDA retained only the listings for NADA 141-137 and NADA 138-939 in those tables. In addition, FDA retained § 558.15(a) through (f). FDA stated it intended to finalize the proposed rule to remove all of § 558.15 once, as part of the DESI program, either the approvals for NADA 141-137 and NADA 138-939 have been withdrawn or part 558, subpart B has been amended to reflect their approvals.

Subsequently, Pennfield filed a supplement to NADA 138-939 for its fixed-combination oxytetracycline/neomycin Type A medicated articles. The supplemental NADA, which provided labeling conforming to the relevant findings of effectiveness announced in the NOOH, was approved on July 2, 2009, and the regulations were amended in § 558.455 of subpart B to reflect that approval (74 FR 40723, August 13, 2009).