

Title 15—Commerce and Foreign Trade

PART 902—NOAA INFORMATION COLLECTION REQUIREMENT UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, in the table in paragraph (b), under the entry “50 CFR”, add an entry in alphanumeric order for “635.4(e)(4)” to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *
(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control No. (all numbers begin with 0648–)
* * * * *	* * * * *
50 CFR

CFR part or section where the information collection requirement is located	Current OMB control No. (all numbers begin with 0648–)
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635.4(e)(4)	– 0205
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[FR Doc. 2015–31782 Filed 12–15–15; 11:15 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of New Animal Drug Applications; Nitarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of three new animal drug applications (NADAs) providing for the use of nitarsone in medicated feed for chickens and turkeys. This action is being taken at the sponsor’s request because these products are no longer manufactured or marketed.

DATES: This rule is effective December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following NADAs that provide for the use of nitarsone in medicated feed for chickens and turkeys because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR Section
007–616	HISTOSTAT 50 (nitarsone) Type A Medicated Article	558.369
141–088	HISTOSTAT 50 (nitarsone)/BMD (bacitracin methylene disalicylate)	558.369
141–132	HISTOSTAT 50/ALBAC (bacitracin zinc)	558.369

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 007–616, 141–088, and 141–132, and all supplements and amendments thereto, is withdrawn, effective December 31, 2015. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Parts 556

Animal drugs, Food.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.60 [Removed]

■ 2. Remove § 556.60.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.4 [Amended]

■ 4. In § 558.4(d), in the “Category II” table, remove the entry for “Nitarsone”.

§ 558.76 [Amended]

■ 5. In § 558.76, remove and reserve paragraph (d)(3)(xiii).

§ 558.78 [Amended]

■ 6. In § 558.78, remove and reserve paragraph (d)(3)(vii).

§ 558.369 [Removed]

■ 7. Remove § 558.369.

Dated: December 11, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31827 Filed 12–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of New Animal Drug Applications; Nitarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) providing for the use of nitarsone in medicated feed for chickens and turkeys. This action is being taken at the sponsor’s request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 31, 2015.
FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug

Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI

49007 has requested that FDA withdraw approval of the following NADAs that provide for the use of nitarosone in medicated feed for chickens and turkeys because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR Section
007-616	HISTOSTAT 50 (nitarosone) Type A Medicated Article	558.369
141-088	HISTOSTAT 50 (nitarosone)/BMD (bacitracin methylene disalicylate)	558.369
141-132	HISTOSTAT 50/ALBAC (bacitracin zinc)	558.369

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 *Notice of withdrawal of approval of application*, notice is given that approval of NADAs 007-616, 141-088, and 141-132, and all supplements and amendments thereto, is hereby withdrawn, effective December 31, 2015.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: December 11, 2015.

Bernadette Dunham,
 Director, Center for Veterinary Medicine.
 [FR Doc. 2015-31828 Filed 12-17-15; 8:45 am]
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9745]

RIN 1545-BL43

Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the health insurance premium tax credit enacted by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, as amended by the Medicare and Medicaid Extenders Act of 2010, the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, and the Department of Defense and Full-Year Continuing Appropriations Act,

2011. These final regulations affect individuals who enroll in qualified health plans through Affordable Insurance Exchanges (Exchanges, sometimes called Marketplaces) and claim the health insurance premium tax credit, and Exchanges that make qualified health plans available to individuals and employers.

DATES: Effective Date: These regulations are effective on December 18, 2015.

Applicability Dates: For dates of applicability, see §§ 1.36B-1(o) and 1.36B-6(g).

FOR FURTHER INFORMATION CONTACT: For general questions on the premium tax credit, Shareen Pflanz, (202) 317-4718; for minimum value, Andrew Braden, (202) 317-7006 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations amending the Income Tax Regulations (26 CFR part 1) under section 36B of the Internal Revenue Code (Code) relating to the health insurance premium tax credit. Section 36B was enacted by the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), and the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the Affordable Care Act). Final regulations under section 36B (TD 9590) were published on May 23, 2012 (77 FR 30377) (2012 section 36B final regulations). On May 3, 2013, a notice of proposed rulemaking (REG-125398-12) was published in the **Federal Register** (78 FR 25909). Written comments responding to the proposed regulations were received. The comments have been considered in connection with these final regulations and are available for public inspection at www.regulations.gov or on request. No public hearing was requested or held. After consideration of all the comments, the proposed regulations are adopted, in part, as amended by this Treasury decision. Some rules proposed under REG-125398-12 on the minimum

value of eligible employer-sponsored plans have been reserved and will be finalized separately under REG-119850-15. Two paragraphs on minimum value have been re-proposed, see REG-143800-14 (80 FR 52678) (2015 proposed minimum value regulations), are finalized in part, and will be finalized in part under REG-143800-14.

Explanation of Revisions and Summary of Comments

1. Definition of Modified Adjusted Gross Income

Section 36B(d)(2) provides that a taxpayer's household income includes the modified adjusted gross income of the taxpayer and the members of the taxpayer's tax family who are required to file an income tax return. The 2012 section 36B final regulations provide that, in computing household income, whether a family member must file a tax return is determined without regard to section 1(g)(7). Under section 1(g)(7), a parent may elect to include a child's gross income in the parent's gross income if certain requirements are met.

The proposed regulations removed "without regard to section 1(g)(7)" from the 2012 section 36B final regulations because that language implied that the child's gross income is included in both the parent's adjusted gross income and the child's adjusted gross income in determining household income. Thus, the proposed regulations clarified that when a parent makes an election under section 1(g)(7), household income includes the child's gross income included on the parent's return only. These final regulations adopt that rule without change and clarify that the modified adjusted gross income of a parent who makes the section 1(g)(7) election includes the child's modified adjusted gross income. Thus, the parent's modified adjusted gross income includes not only the child's gross income but also the child's tax-exempt interest and nontaxable Social Security income, which are excluded from gross