DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 558
[Docket No. FDA–2012–N–0002]

New Animal Drugs for Use in Animal Feeds; Tiamulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The supplemental NADA provides for approval of a new concentration of a Type A medicated article.

DATES: This rule is effective April 23, 2012.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, email: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc. (Novartis), 3200 Northline Ave., Suite 300, Greensboro, NC 27408, filed a supplement to NADA 139–472 for DENAGARD (tiamulin hydrogen fumarate) Type A medicated articles for use of a new product formulation in medicated swine feed. The supplemental NADA is approved as of January 6, 2012, and the regulations in 21 CFR 558.4 and 558.600 are amended to reflect the approval.

The Agency has determined under 21 CFR 25.33 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.

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 in 21 CFR Part 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

2. In paragraph (d) of § 558.4, in the “Category II” table, revise the entries for “Tiamulin” to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Assay limits percent</th>
<th>Type B maximum (100x)</th>
<th>Assay limits percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tiamulin hydrogen fumarate</td>
<td>90–115</td>
<td>10 g/lb</td>
<td>90–115/70–130</td>
</tr>
</tbody>
</table>

1 Percent of labeled amount.
2 Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.
3. In § 558.600, revise paragraph (a) and the heading of the first column in the table in paragraph (e)(1) to read as follows:

<table>
<thead>
<tr>
<th>Tiamulin hydrogen fumarate in grams per ton</th>
<th>* * *</th>
<th>* * *</th>
<th>* * *</th>
<th>* * *</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ 558.600 Tiamulin.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Specifications. Type A article containing 363.2 grams of tiamulin hydrogen fumarate per pound.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) * * * * * *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dated: April 17, 2012.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 570

[Docket No. FR–5181–F–02]

RIN 2506–AC22

State Community Development Block Grant Program: Administrative Rule Changes

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Final rule.

SUMMARY: This final rule makes changes to several sections of the regulations for the Community Development Block Grant (CDBG) program for states (State CDBG program). This final rule streamlines and updates the regulations to reflect statutory changes, clarifies the program income requirements, provides other clarifications to the State CDBG program regulations, and makes a conforming change to the regulations applicable to the CDBG Entitlement program. This final rule also provides additional flexibility to states in their administration of the program. The final rule follows publication of an October 17, 2008, proposed rule and takes into consideration the public comments received on the proposed rule.

DATES: Effective Date: May 23, 2012.

FOR FURTHER INFORMATION CONTACT: Eva C. Fontheim, Community Planning and Development Specialist, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7182, Washington, DC 20410; telephone number 202–708–1322 (this number is not toll-free). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 2008, at 73 FR 61757, HUD published for public comment a proposed rule that would revise HUD’s regulations for the State CDBG program in 24 CFR part 570, subpart I, in order to conform the regulations to current statutory requirements concerning program income, and to provide additional flexibility to states in implementing their programs. Title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301–5320) (HCDA) established the statutory framework for the CDBG program. The primary statutory objective of the CDBG program is to develop viable communities, by providing decent housing and a suitable living environment and by expanding economic opportunities, principally for persons of low- and moderate-income. HUD’s regulations implementing the CDBG program are located in 24 CFR part 570 (entitled “Community Development Block Grants”).

Under the State CDBG program, states have the opportunity to administer CDBG funds for nonentitlement areas. Nonentitlement areas include those units of general local government that do not receive CDBG funds directly. States participating in the State CDBG program award grants only to units of general local government that carry out development activities. Annually, each state develops funding priorities and criteria for selecting projects. HUD’s role under the State CDBG program is to ensure state compliance with federal laws, regulations, and policies. The regulations for the State CDBG program are codified in subpart I of the part 570 regulations.

The proposed regulatory amendments described in the October 17, 2008, proposed rule were designed to clarify how HUD will administer the State CDBG program. HUD proposed to streamline and update the regulations to reflect statutory changes, clarify the program income requirements, and provide other clarifications to the State CDBG regulations that will provide states with additional flexibility in their administration of the program. Interested readers should refer to the preamble to the October 17, 2008, proposed rule for additional information on the proposed regulatory changes to the State CDBG program.

II. This Final Rule: Changes to the October 17, 2008, Proposed Rule

This final rule follows publication of the October 17, 2008, proposed rule and takes into consideration the public comments received on the proposed rule. The public comment period on the proposed rule closed on December 16, 2008. HUD received eight responses. Commenters included one public interest group and seven units of local government. Most of the public comments pertained to the provisions of the proposed rule concerning program income requirements. After careful consideration of the issues raised by the commenters, HUD has decided to adopt an amended version of the proposed rule. Specifically, HUD has made the following changes to the October 17, 2008, proposed rule:

1. Administrative Expense Cap Time Period. The final rule clarifies, at § 570.489(a)(1), that the program income included in the calculation determining the amount of allowable administrative and technical assistance per program year is all of the program income received in the program year, regardless of the fiscal year in which the state grant funds were appropriated that generated the program income.

2. Identifies Parties in the Grant Agreement for Calculating Program Income. Section 570.489(e)(2)(v) of the final rule specifies that the grant agreement referred to in this section is between the state and the unit of general local government.

3. Entitlement Jurisdictions Receive Only an Incidental Benefit From State CDBG Program Expenditures. The final rule, at § 570.486(c), no longer mandates...