DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73


Listing of Color Additives Exempt From Certification; Paracoccus Pigment; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 17, 2009, for the final rule that appeared in the Federal Register of November 16, 2009. The final rule amended the color additive regulations to provide for the safe use of paracoccus pigment as a color additive in the feed of salmonid fish to enhance the color of their flesh.

DATES: The effective date for the final rule that published in the Federal Register on November 16, 2009 (74 FR 58843) is confirmed as December 17, 2009.


SUPPLEMENTARY INFORMATION: In the Federal Register of November 16, 2009 (74 FR 58843), FDA amended the color additive regulations to add 21 CFR 73.352 to provide for the safe use of paracoccus pigment as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FDA gave interested persons until December 16, 2009, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the Federal Register on November 5, 2009, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, notice is given that no objections or requests for a hearing were filed in response to the November 16, 2009, final rule. Accordingly, the amendments issued thereby became effective December 17, 2009.

Dated: January 22, 2010.

Mitchell A. Cheeseman, Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73


Listing of Color Additives Exempt From Certification; Astaxanthin Dimethylisuccinate; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 8, 2009, for the final rule that appeared in the Federal Register of November 5, 2009. The final rule amended the color additive regulations to provide for the safe use of astaxanthin dimethylisuccinate as a color additive in the feed of salmonid fish to enhance the color of their flesh.

DATES: The effective date for the final rule published in the Federal Register of November 5, 2009 (74 FR 57248) is confirmed as December 8, 2009.


SUPPLEMENTARY INFORMATION: In the Federal Register of November 5, 2009 (74 FR 57248), FDA amended the color additive regulations to add § 73.37 (21 CFR 73.37) to provide for the safe use of astaxanthin dimethylisuccinate as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FDA gave interested persons until December 7, 2009, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the Federal Register of November 5, 2009, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, notice is given that no objections or requests for a hearing were filed in response to the November 5, 2009, final rule. Accordingly, the amendments issued thereby became effective December 8, 2009.

Dated: January 22, 2010.

Mitchell A. Cheeseman, Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0002]

New Animal Drugs for Use in Animal Feeds; Ractopamine; Monensin

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 an original new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The NADA provides for use of single-ingredient Type A medicated articles containing ractopamine hydrochloride and monensin to formulate two-way combination Type C medicated feeds for finishing hen and tom turkeys.

DATES: This rule is effective February 5, 2010.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8101, e-mail: linda.wilmot@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly
Standards Act of 1974 provides that

Housing Construction and Safety

Commissioner, HUD.

Secretary for Housing—Federal Housing

SUMMARY:

ACTION:

AGENCY:

Committee Processes

That Are Subject to Consensus

and Other Orders: HUD Statements

Construction and Safety Standards

Federal Manufactured Home

RIN 2502–AI77

24 CFR Parts 3280 and 3282

[Docket No. FR–5343–IN–01]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING

and Urban Development

Effective Date:

February 5, 2010.

FOR FURTHER INFORMATION CONTACT:

William W. Matchneer III, Associate

Deputy Assistant Secretary for

Regulatory Affairs and Manufactured

Housing, Office of Manufactured

Housing Programs, Department of

Housing and Urban Development, 451

Seventh Street, SW., Room 9164,

Washington, DC 20410; telephone

number 202–708–6401 (this is not a
toll-free number). Persons with hearing

or speech impairments may access this

number via TTY by calling the toll-free

Federal Information Relay Service at

1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The National Manufactured Housing

Construction and Safety Standards Act

of 1974 (42 U.S.C. 5401–5426) ("the Act"), as

amended by the Manufactured

Housing Improvement Act of 2000 (Title

VI, Pub. L. 106–659), provides for the

establishment and revision of Federal

construction and safety standards for

manufactured housing, as well as for

procedural and enforcement regulations

and interpretive bulletins related to

implementation of these standards.

Section 604(a) of the Act provides,
among other things, the process for the
development, proposal, and issuance of
revisions of Federal construction and

safety standards, which govern the

construction, design, and performance of

a manufactured home. Section 604(a)
establishes a consensus committee,

which is comprised of representatives of

manufactured housing producers and

manufactured housing requirements are subject to proposal,

review, and comment processes

involving a consensus committee. The

consensus committee includes

representatives of manufactured

housing producers and users, as well as

general interest and public officials.

This rule interprets the statutory

requirement to clarify the types of

statements that are subject to the

proposals, review, and comment

processes.

DATES: Effective Date: February 5, 2010.

Federal Manufactured Home

Construction and Safety Standards

and Other Orders: HUD Statements

That Are Subject to Consensus

Committee Processes

AGENCY: Office of the Assistant

Secretary for Housing—Federal Housing

Commissioner, HUD.

ACTION: Interpretive rule.

SUMMARY: The National Manufactured

Housing Construction and Safety

Standards Act of 1974 provides that

Ractopamine in

grams/ton

Combination in

grams/ton

Indications for use

Limitations

Sponsor

(iii) 4.6 to 11.8 (5 to 13

ppm)

Monensin 54 to 90

Finishing hen turkeys: As in para-

graph (e)(3)(i) of this section; and

for the prevention of coccidiosis in

growing turkeys caused by Eimeria

adenoeides, E. meleagritms and

E. gallopavonis.

Feed continuously as sole ration dur-

ing the last 7 to 14 days prior to

slaughter. See §558.355(d).

000986

(iv) 4.6 to 11.8 (5 to 13

ppm)

Monensin 54 to 90

Finishing tom turkeys: As in para-

graph (e)(3)(ii) of this section; and

for the prevention of coccidiosis in

growing turkeys caused by Eimeria

adenoeides, E. meleagritms and

E. gallopavonis.

Feed continuously as sole ration dur-

ing the last 14 days prior to slaugh-

ter. Feeding ractopamine to tom

turkeys during periods of excessive

heat can result in increased mor-

tality. See §558.355(d).

000986

Therefore, under the Federal Food,

Drug, and Cosmetic Act and under the

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 §558.500, add paragraphs

(e)(3)(iii) and (e)(3)(iv) to read as

follows:

§558.500 Ractopamine.

* * * * *

(e) * * *

(3) * * *

Animal drugs, Animal feeds.

1061, Rockville, MD 20852, between 9

a.m. and 4 p.m., Monday through

Friday.

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,

either 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


List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.