description and analysis of final rules that will have significant economic impact on a substantial number of small entities. This Final Rule concerns an interpretation of current Commission regulations and practices. The Commission certifies that it will not have a significant economic impact upon participants in Commission proceedings. An analysis under the RFA is not required.

VII. Document Availability

13. In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission’s Home Page (http://www.ferc.gov) and in the Commission’s Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

14. From the Commission’s Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

15. User assistance is available for eLibrary and the Commission’s Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

VIII. Effective Date

16. The Commission is issuing this rule as a Final Rule without a period for public comment. Under 5 U.S.C. 553(b)(A), notice and comment procedures are unnecessary for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice...” This rule merely provides the public with guidance concerning the existing regulation and reminds the general public of the rules available to the public at the Commission’s open meetings. The rule will not significantly affect regulated entities or the general public.

17. These regulations are effective April 13, 2015.

List of Subjects in 18 CFR Part 375

Open Meetings.

Issued: March 9, 2015.

By the Commission.
Kimberly D. Bose,
Secretary.

In consideration of the foregoing, the Commission amends Part 375, Chapter I, Title 18, Code of Federal Regulations, as follows:

PART 375—THE COMMISSION

1. The authority citation for Part 375 continues to read as follows:


2. Section 375.203 is amended by adding paragraphs (b)(1)(i) and (ii) and revising paragraph (b)(2) to read as follows:

§375.203 Open meetings.

* * * * *

(b) * * * * *

(1) * * *

(i) “Observe” does not include participation or disruptive conduct, and persons engaging in such conduct will be removed from the meeting.

(ii) The right of the public to observe open meetings does not alter those rules which relate to the filing of motions, pleadings, or other documents. Unless such pleadings conform to the other procedural requirements, pleadings based upon comments or discussions at open meetings, as a general rule, will not become part of the official record, will receive no consideration, and no further action by the Commission will be taken thereon.

(2) To the extent their use does not interfere with the conduct of open meetings, electronic audio and visual recording equipment may be used by a seated observer at an open meeting.

* * * * *

[FR Doc. 2015–05689 Filed 3–12–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments: Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments—Small Entity Compliance Guide”. The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled “Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.”

DATES: The SECG will be available as of March 13, 2015. Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written comments for single copies of the SECG to the Office of Nutrition, Labeling and Dietary Supplements, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the SECG.

Submit electronic comments on the SECG to http://www.regulations.gov. Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 1, 2014 (79 FR 71156), we issued a final rule requiring nutrition labeling of standard menu items in restaurants and similar retail food establishments (the final rule). The final rule, which is codified at 21 CFR 101.11, is effective December 1, 2015.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.
We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents our current thinking on nutrition labeling of standard menu items in restaurants and similar retail food establishments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA’s final rule that published in the Federal Register of December 1, 2014 (79 FR 71156), and that will be effective on December 1, 2015. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). In compliance with the PRA (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of the final rule to OMB for review. FDA will publish a document in the Federal Register announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Comments

Interested persons may submit either electronic comments regarding the SECG to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at either http://www.fda.gov/Food/Guidance Regulation/GuidanceDocuments RegulatoryInformation/default.htm or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 6, 2015.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2015–05590 Filed 3–12–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTIONS: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during November and December 2014. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsorship of eight NADAs and nine ANADAs, and to make correcting amendments for a drug labeler code.

DATES: This rule is effective March 13, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HVf–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during November and December 2014, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/ CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

In addition, Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, has transferred ownership of, and all rights and interest in, the following approved applications to Pharmgate LLC, 161 North Franklin Turnpike, Suite 2C, Ramsey, NJ 07446:

<table>
<thead>
<tr>
<th>File No.</th>
<th>Product name</th>
<th>21 CFR Cite</th>
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<tbody>
<tr>
<td>065–480</td>
<td>Chlortetracycline Soluble Powder</td>
<td>...</td>
</tr>
<tr>
<td>138–934</td>
<td>PENNCHLOR SP (chlortetracycline, sulfamethazine, penicillin) Type A medicated articles</td>
<td>558.145.</td>
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<tr>
<td>138–935</td>
<td>PENNCHLOR (chlortetracycline) Type A medicated articles</td>
<td>558.128.</td>
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<tr>
<td>138–936</td>
<td>PENNOX (oxytetracycline) Type A medicated articles</td>
<td>558.450.</td>
</tr>
<tr>
<td>138–937</td>
<td>NEO–OXY (neomycin sulfate and oxytetracycline) Type A medicated articles</td>
<td>558.625.</td>
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<tr>
<td>140–680</td>
<td>TLYAN (tylosin phosphate) Type A medicated articles</td>
<td>558.630.</td>
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<tr>
<td>140–681</td>
<td>TLYAN SulfG (tylosin phosphate and sulfamethazine) Type A medicated articles</td>
<td>558.455.</td>
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<tr>
<td>141–137</td>
<td>PENITRACIN (bacitracin methylenedisalicylate) 50 Type A medicated article</td>
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<tr>
<td>200–026</td>
<td>PENNOX 343 (oxytetracycline)</td>
<td>Not codified.</td>
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<tr>
<td>200–154</td>
<td>PENNOX 200 (oxytetracycline)</td>
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<td>200–295</td>
<td>PENNCHLOR 64 (chlortetracycline)</td>
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<td>200–314</td>
<td>PENNCHLOR S (chlortetracycline)</td>
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<td>200–355</td>
<td>PENNCHLOR (chlortetracycline)/COBAN (monensin)</td>
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<td>200–356</td>
<td>PENNCHLOR (chlortetracycline)/DENAGARD (tiamulin)</td>
<td>558.600.</td>
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