

letter to permit holders that also serves as small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the Northwest Regional Office, and the guide, i.e., permit holder letter, will be sent to all holders of permits for the fishery. The guide and this final rule will be available upon request.

This final rule contains a collection-of-information requirement subject to the PRA that has been approved by the Office of Management and Budget (OMB) under control number 0648-0599 (expires 12/31/12). The public reporting burden for the Trawl Identification of Ownership Interest Form is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection information. This form is estimated to cost approximately \$19.15 per response (including the respondent's time (\$8.51), mailing, photocopying, and notary fee). There is no fee for this form. Send comments regarding these burden estimates or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS, Northwest Region (see ADDRESSES) and by e-mail to [David\\_Rostker@omb.eop.gov](mailto:David_Rostker@omb.eop.gov), or fax to 202-395-7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

## List of Subjects

### 15 CFR Part 902

Reporting and recordkeeping requirements.

### 50 CFR Part 660

Fisheries, Fishing, and Indian Fisheries.

Dated: January 25, 2010.

### Samuel D. Rauch III,

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

■ For the reasons set out in the preamble, 15 CFR Chapter IX and 50 CFR Chapter VI are amended as follows:

## 15 CFR Chapter IX

### PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS 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, paragraph (b), under "50 CFR", the entry "660.337" is added in numerical order 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 number (all numbers begin with 0648—)
*	*
50 CFR *	*
660.337 *	-0599 *

## 50 CFR Chapter VI

### PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

**Authority:** 16 U.S.C. 1801 *et seq.*

■ 2. A new § 660.337 is added to read as follows:

#### § 660.337 Trawl rationalization program - data collection requirements.

(a) Ownership reporting requirements - (1) In 2010, NMFS will send a Trawl Identification of Ownership Interest Form to the current address on record requesting information from participants in the trawl fishery. Receipt of this form does NOT prequalify these persons for quota share nor does it guarantee that they will qualify for quota share under a future trawl rationalization program. The following participants in the trawl fishery must complete and return the form to NMFS:

(i) Owners of each limited entry permit endorsed for trawl gear;

(ii) Owners of each vessel registered to a limited entry permit endorsed for trawl gear (i.e., permit holder) if not identical to the permit owner covered by paragraph (a)(1)(i) of this section;

(iii) Owners of each vessel registered to a Pacific whiting vessel license that are not covered by paragraphs (a)(1)(i) and (ii) above; and

(iv) First receivers issued current Pacific whiting first receiver exempted fishing permits.

(2) Supporting documentation.

(i) Business entities completing the Trawl Identification of Ownership Interest Form are required to submit the following:

(A) A corporate resolution or any other credible documentation as proof that the representative of the entity is authorized to act on behalf of the entity; and

(B) Proof that the business entity was established and is currently recognized as active under the laws of the United States or any state.

(ii) After review of the Trawl Identification of Ownership Interest Form, NMFS may require the following additional documentation:

(A) Articles of incorporation, a notarized contract, or any other credible documentation that identifies each person who owns an interest in the entity and their percentage of ownership;

(B) A certified copy of the current vessel document (United States Coast Guard or state) as evidence of vessel ownership; or

(C) Such other relevant, credible information as the applicant may submit, or as the SFD or the Regional Administrator may request or require.

(3) Deadline. Persons listed in paragraph (a)(1) will be provided at least 60 calendar days to submit completed forms. All forms must be completed and returned to NMFS with a postmark no later than the deadline date of May 1, 2010.

(b) [Reserved]

[FR Doc. 2010-1877 Filed 1-28-10; 8:45 am]

BILLING CODE 3510-22-S

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### 18 CFR Parts 35, 131, 154, 157, 250, 281, 284, 300, 341, 344, 346, 347, 348, 375 and 385

[Docket No. RM01-5-000]

### Electronic Tariff Filings

Issued January 21, 2010.

**AGENCY:** Federal Energy Regulatory Commission.

**ACTION:** Order establishing procedures relating to tariffs filed electronically.

**SUMMARY:** The adoption of electronic tariff filing necessitates changes in the Commission's processing of tariff filings. This order identifies the ways in which such changes affect aspects of Commission procedures, particularly the determination of statutory filings and statutory action dates, as well as changes in docketing procedures.

**DATES: Effective date:** This order is effective January 29, 2010. **Applicability date:** This order becomes applicable when tariff filings are submitted in electronic format.

**FOR FURTHER INFORMATION CONTACT:**

H. Keith Pierce (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8525, [Keith.Pierce@ferc.gov](mailto:Keith.Pierce@ferc.gov).

Anthony Barracchini (IT Information), Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8940, [Anthony.Barracchini@ferc.gov](mailto:Anthony.Barracchini@ferc.gov).

Andre Goodson (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8560, [Andre.Goodson@ferc.gov](mailto:Andre.Goodson@ferc.gov).

**SUPPLEMENTARY INFORMATION:**

1. In Order No. 714,<sup>1</sup> the Commission adopted regulations requiring that, starting April 1, 2010, all tariffs and tariff revisions filed with the Commission must be filed electronically according to a format developed through collaboration between Commission staff and the wholesale electric and gas quadrants of the North American Energy Standards Board, and representatives from the Association of Oil Pipelines. The adoption of electronic tariff filing provides the framework for a more efficient document processing system as well as providing a user-friendly interface from which the Commission, its staff, and the public may retrieve and review tariffs.

2. The adoption of electronic tariff filing necessitates changes in the business practices used by the Commission to process tariff filings. This order identifies ways in which such changes affect aspects of Commission procedures, particularly the determination of whether a filing is a statutory filing, and the statutory action date, as well as changes in docketing procedures.

<sup>1</sup> Electronic Tariff Filings, Order No. 714, 73 FR 57515 (Oct. 3, 2008), FERC Stats. & Regs ¶ 31,276 (2008).

**Statutory Filings**

3. As the Commission explained in Order No. 714, the electronic format developed through the collaborative process relies upon the use of metadata (or information) about the tariff filing, including such data elements as the type of filing that is being made, the proposed effective date of proposed tariff changes, and the version number of the effective tariff.<sup>2</sup> As the Commission explained, these data elements "are required to properly identify the nature of the tariff filing, organize the tariff database, and maintain the proper relationship of tariff provisions in relation to other provisions."<sup>3</sup>

4. The Commission will be using these data elements to establish statutory filing and other procedural dates.<sup>4</sup> The Commission will use the "Type of Filing" code (`filng_type`) together with the "Tariff Record Proposed Effective Date" (`proposed_effective_date`) to establish whether a filing is statutory and the applicable statutory timelines.

5. All filers making statutory filings must choose a statutory filing type and include a proposed effective date to have their filings treated as statutory filings upon which the Commission must act within statutorily-established time frames. That is, the filing type selected by the filer will determine the type of filing and whether the filing is to be treated as a statutory filing. Any discrepancy between the description of the filing in the transmittal letter (or other pleading) and the Type of Filing code chosen will be resolved in favor of the Type of Filing code.<sup>5</sup> Because the Commission is using the electronic

<sup>2</sup> These data elements, or codes, are described in the *Implementation Guide for Electronic Filing of Parts 35, 154, 284, 300, and 341 Tariff Filing* (Implementation Guide), found on the Commission's Web site, <http://www.ferc.gov/docs-filing/etariff/implementation-guide.pdf>.

<sup>3</sup> Order No. 714 at P 23. See The National Center for State Courts, *Standards for Electronic Filing Processes (Technical and Business Approaches)*, Standard 1.1F (2003) (concluding that the responsibility for data entry needs to be assigned to the filer, since it has the greatest familiarity with the data to be entered), [http://www.ncsconline.org/d\\_tech/standards/Documents/pdfdocs/Recommended\\_%20Process\\_%20standards\\_02\\_26\\_03.pdf](http://www.ncsconline.org/d_tech/standards/Documents/pdfdocs/Recommended_%20Process_%20standards_02_26_03.pdf).

<sup>4</sup> A statutory filing is a filing made pursuant to section 4 of the Natural Gas Act (NGA), section 205 of the Federal Power Act (FPA), or section 6 of the Interstate Commerce Act (ICA) to revise rates or terms and conditions of service.

<sup>5</sup> For example, if the transmittal letter states that a statutory FPA section 205 filing is contemplated, but the Type of Filing code selected represents a compliance filing, the Commission will treat the filing as a compliance filing, which is not subject to action within the period prescribed by FPA section 205.

metadata to establish statutory action dates throughout its electronic systems, the primacy of the Type of Filing code is necessary to ensure the integrity of Commission processes and to ensure Commission action on such filings within the time period provided under the appropriate statute.<sup>6</sup> While Commission staff will try, where possible, to notify a filer of discrepancies between its transmittal letter and the Type of Filing code it selected, the Type of Filing code selected will govern the appropriate filing type and thus whether and what actions dates may be applicable.<sup>7</sup>

6. Similarly, the Commission will be using the Tariff Record Proposed Effective Date code to establish the proposed effective date for any statutory filing.<sup>8</sup> As is current practice, the date established by the Tariff Record Proposed Effective Date, if that date is after the otherwise statutorily-established effective date, will establish the date on which, by statute, a tariff filing would go into effect by operation of law in the absence of Commission action.<sup>9</sup> In a tariff filing that contains different proposed effective dates for different proposed tariff changes, the earliest proposed effective date will establish the proposed effective date for determining the date on which the filing would go into effect in the absence of Commission action.<sup>10</sup> While the Commission will continue its current practice of considering requests in

<sup>6</sup> The Type of Filing code will be used in all of the Commission's electronic systems to establish the applicable statutory action dates, and so, notwithstanding a filing party's wish expressed in its transmittal letter or in other pleadings, the Commission may not review a filing that is incorrectly coded within the time period requested by a filing party in such pleadings.

<sup>7</sup> Commission staff's efforts in this regard are intended simply as a voluntary and informal aid to filers, and any action or failure on the part of Commission staff will not bind or otherwise affect how the Commission processes such filings. See 18 CFR 388.104(a) (2009); *accord, e.g.*, 18 CFR 154.8 (2009). It is, and remains, the filer's responsibility to ensure that it is selecting the appropriate Type of Filing code, as well as accurately providing any other metadata.

<sup>8</sup> In order to constitute a statutory tariff filing, the filer, therefore, must both select a statutory Type of Filing code and include a Tariff Record with a Tariff Record Proposed Effective Date.

<sup>9</sup> For example, if the Tariff Record Proposed Effective Date is after the otherwise applicable statutorily-established effective date, the statutory period will be extended until the Tariff Record Proposed Effective Date.

<sup>10</sup> As explained in the Implementation Guide, for statutory filings with indeterminate effective dates, for example, where the effective date is contingent on Commission approval, plant construction, or the closing of a plant sale, filers must still include a Tariff Record Proposed Effective Date, but should set that date to 12/31/9998. Implementation Guide, at 10, <http://www.ferc.gov/docs-filing/etariff/implementation-guide.pdf>.

transmittal letters or other pleadings for issuance of orders on an expedited basis, statements in transmittal letters or other pleadings will *not* establish statutory action dates for tariff filings.

7. Because of the importance of the Type of Filing code and the Tariff Record Proposed Effective Date, these metadata will be included in the electronic notices sent to the filers and posted on eLibrary.<sup>11</sup> Filers should check these sources carefully to verify that their tariff filings and proposed effective dates are what they intended.

8. Filers also need to be careful when making combined filings, *i.e.*, filings whose different parts would, if filed individually, have different Type of Filing codes.<sup>12</sup> Each filing can have only one Type of Filing code, and so the treatment of any combined filing will depend on the particular Type of Filing code chosen.<sup>13</sup>

#### Docketing Procedures

9. The Commission will use the metadata supplied with the tariff filing to help speed up its docketing and notice process. As far as possible, these data will permit docketing that closely parallels current practice. However, some of the docket prefixes previously used may not be assigned to electronic tariff filings and these filings will be assigned only a single docket number rather than multiple docket numbers as may have occurred in the past.

10. Procedures for identifying root and subsequent subdockets<sup>14</sup> will remain the same for the vast majority of compliance and other filings. However, in a few cases, parties will experience differences, particularly for compliance filings made in the context of complaint cases.

11. Subdockets for compliance filings will be established based on the

<sup>11</sup> An example of how eLibrary will display the metadata for an electronic tariff filing is posted at <http://www.ferc.gov/EventCalendar/Files/20091119114331-Example%20eTariff%20eLibrary%20Rendition.rtf>.

<sup>12</sup> The Commission's regulations and policies already prohibit combined filings in some situations. See 18 CFR 154.203 (2009) (compliance filings cannot be combined with any other type of filing); *Calpine Eastern Corporation*, 97 FERC ¶ 61,078, at 61,382 (2001) (cannot combine filings made in compliance with a prior Commission order with new FPA section 205 filings).

<sup>13</sup> Instead of combining filings, filers can make separate filings for each type of filing contemplated—each filing containing the portions relevant to the specific filing type.

<sup>14</sup> The Commission typically assigns a root docket number to an initial filing and then adds subdockets to later filings in the same proceeding. As an illustration, for Docket No. ER12-6789-000, the root docket number is "ER12-6789" and the subocket is "000." When a subsequent compliance filing is made, the root docket is retained and the subocket will be incremented, usually by 1, so that the new docket number will be ER12-6789-001.

metadata provided by the pipeline or utility making the filing. Each pipeline or utility is required to identify every filing using a discrete number, "Filing Identifier" (filing\_id). When making filings related to or associated with a prior filing (such as a compliance filing), the pipeline or utility must include the Filing Identifier of the prior filing that is associated with its current filing. (The Filing Identifier of the initial filing will be included as the "Associated Filing Identifier" (associated\_filing\_id) in the subsequent filing). For example, if the pipeline or utility is making a compliance filing, it will include as the Associated Filing Identifier in the compliance filing, the Filing Identifier it assigned to the initial tariff filing giving rise to the compliance filing. That Associated Filing Identifier will permit the Commission to determine the relevant root docket number assigned to the initial tariff filing, so that a subocket for the compliance filing can be assigned.

12. However, in those circumstances in which the pipeline or utility does not include (in a subsequent filing) the Filing Identifier of its initial filing, the root docket number for the initial proceeding will not be available. Accordingly, a new root docket number will be assigned to the compliance filing. The practice of assigning a new root docket parallels the Commission's typical practice with respect to compliance filings in rulemaking proceedings, in which each pipeline's or utility's individual filing to comply with the rule typically receives a new root docket number.

13. However, new root docket numbers may be assigned in situations in which subdockets traditionally had been assigned manually and new procedures need to be followed in these circumstances. A common situation in which this will occur will be during the implementation phase of electronic tariff filing. New root docket numbers will be assigned to compliance filings when companies have outstanding compliance obligations at the time they make their original, baseline tariff filings. Because the original tariff filing giving rise to the compliance obligation will not be part of the pipeline's or utility's electronic database, it will not have a Filing Identifier and therefore the pipeline or utility will not be able to include the Filing Identifier in the compliance filing, and the compliance filing will be assigned a new root docket number.

14. This situation also may occur on a limited scale on an ongoing basis. For example, in complaint cases, the filing initiating the complaint is not filed by

the pipeline or utility, but rather by a third-party, typically a customer. In the process of resolving the complaint, the Commission may require the pipeline or utility to file a revision to its tariff. In such a circumstance, the pipeline or utility will not have an initial filing in its database with which to associate the compliance filing. Therefore, as described above, the compliance filing made through the electronic tariff filing portal will receive a new root docket, rather than a subocket from the original complaint case. In other words, the compliance filing in a complaint proceeding will parallel the situation in which the pipeline or utility is complying with a rulemaking, and the compliance filing will receive a new root docket.<sup>15</sup>

15. In situations in which new root dockets are assigned to compliance filings, the pipeline or utility making the filing still is required to serve the compliance filing on all parties in the original docket.<sup>16</sup> For example, in a complaint case, the pipeline or utility will need to serve the compliance filing on all parties in the original complaint docket giving rise to the compliance obligation.

16. In order to establish a simple and uniform method for determining parties and service lists when a new root docket is established, the Commission will follow its existing practice with respect to the need to intervene. Currently, parties who have intervened in initial proceedings do not have to re-intervene in subdockets.<sup>17</sup> However, when the Commission establishes new root dockets (such as for compliance with rulemaking proceedings), intervention is required to become a party to the new root docket proceeding and to appear on the service list for that proceeding.<sup>18</sup> The same approach will be taken whenever a new root docket is assigned in a compliance proceeding; those wishing to become parties to a new root docket will have to intervene in that docket. A simple-to-apply rule will help

<sup>15</sup> The complaint proceeding will determine whether the pipeline or utility is in violation of its tariff or whether the tariff is unjust and unreasonable. The compliance proceeding focuses on whether the filing by the pipeline or utility satisfies the Commission's determination in the complaint proceeding.

<sup>16</sup> If service is made electronically by including a link to the document in the Commission's eLibrary system, parties will be notified of the new root docket assigned to the compliance filing. 18 CFR 385.2010(f)(3) (2009) (providing for service through "the transmission of a link to that document in the Commission's eLibrary system").

<sup>17</sup> The Commission maintains one service list for root dockets and all subdockets, not individual service lists for each subocket.

<sup>18</sup> 18 CFR 385.214 (requiring intervention to become a party).

ensure that the parties to proceedings are known to each other and to the Commission and that service of pleadings and orders is provided to all parties.

17. Moreover, to permit the easy identification of related filings for compliance filings receiving new root dockets,<sup>19</sup> pipelines and utilities are urged to include as part of their eFiling description an indication that they are making a compliance filing and the docket number to which they are complying. This filing description will appear in the Commission's notice and will aid in the identification of the relationship between the compliance filing and the original proceeding.

#### *The Commission Orders*

(A) The procedures described in the body of this order will apply to tariff filings that are submitted in electronic format.

(B) The Secretary shall publish a copy of this order in the **Federal Register**.

By the Commission. Commissioner Norris voting present.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010-1538 Filed 1-28-10; 8:45 am]

**BILLING CODE 6717-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 522**

**[Docket No. FDA-2010-N-0002]**

#### **Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid**

**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 Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment of lower respiratory tract infections in horses.

**DATES:** This rule is effective January 29, 2010.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary

<sup>19</sup> These will be filings without the Filing Identifier of a related filing.

Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St, New York, NY 10017, filed a supplement to NADA 141-209 for EXCEDE (ceftiofur crystalline free acid) Sterile Suspension. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*. The application is approved as of December 16, 2009, and the regulations are amended in 21 CFR 522.313a to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of 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 522**

Animal drugs.

■ 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 522 is amended as follows:

#### **PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. In § 522.313a, add paragraph (e)(3) to read as follows:

#### **§ 522.313a Ceftiofur crystalline free acid.**

\* \* \* \*

(e) \* \* \*

(3) *Horses*—(i) *Amount.* Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations.* Do not use in horses intended for human consumption.

Dated: January 22, 2010.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2010-1790 Filed 1-28-10; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 524**

**[Docket No. FDA-2010-N-0002]**

#### **Ophthalmic and Topical Dosage Form New Animal Drugs; Miconazole, Polymixin B, and Prednisolone Suspension**

**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 new animal drug application (NADA) filed by Janssen Pharmaceutica NV. The NADA provides for use of miconazole nitrate, polymixin B sulfate, and prednisolone acetate for the treatment of otitis externa in dogs.

**DATES:** This rule is effective January 29, 2010.

#### **FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium, filed NADA 141-298 that provides for veterinary prescription use of SUROLAN (miconazole nitrate, polymixin B sulfate, and prednisolone acetate) Otic Suspension in dogs for the treatment of otitis externa associated with