



ANIMAL HEALTH

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Department of Health & Human Services
Food & Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, room 1061
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PETITION FOR RECONSIDERATION

Docket No. 06P-0093/CP1

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food & Drugs in Docket No. 06P-0093/CP1.

A. Decision involved

In a response dated 5 May 2006 to the subject Suitability Petition filed on 1 March 2006, the Commissioner denied a request by the petitioner, ECO LLC, for permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug. The approved new animal drug is Merial Ltd's Ivomec® (ivermectin) injection 1% (NADA 128-409). The subject of the petition is Ecomectin™ (ivermectin) injection 2%. The proposed product would contain twice the concentration of ivermectin (2% versus 1%) administered in a dose volume one-half that of the pioneer's product.

The Commissioner stated that, based on the increase in strength (concentration) of ivermectin, the petitioner will need to evaluate target animal safety and effectiveness in an original new animal drug application (NADA).

B. Action requested

The petitioner, ECO LLC, respectfully asks:

- (i) That the Commissioner reconsiders the denial of the subject Suitability Petition.
- (ii) That the Commissioner grants the petitioner's request for permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug as summarized above.

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C. Statement of grounds

1. A change in product strength is one of five variances in the pioneer product which can be sought through a Suitability Petition under §512(n)(3) of the FFDCFA, as amended.
2. The pioneer and the petitioner's products are both true solutions with same active and inactive ingredients. Neither the dose rates of active ingredient per pound body weight in cattle and swine nor the route of administration will differ.
3. Although the concentration in the proposed product is 2% (versus 1% in the pioneer product), the total amount of active ingredient that will be administered will be the same by virtue of the dosage volume being one-half.
4. Because the absolute amount of additional active ingredient in the proposed product is small (from 1% to 2%), the amounts of inactive ingredients in the proposed product will change little from those contained in the pioneer product. The total amount of inactive ingredients in the proposed product will decrease from 99% to 98%.
5. The quantity of product that would be injected into the target animals will be halved. This will decrease the likelihood of tissue and carcass damage (bruising) during administration. The likelihood of rejection of carcass product at or near the injection site during processing at the abattoir will decrease accordingly.
6. Because of the above factors, the petitioner believes that effectiveness and human consumer and target animal safety of the proposed product will not be adversely affected.

This submission includes an original and two additional copies.

ECO Animal Health develops and markets animal health products worldwide. In the United States, it is the animal health division of ECO LLC which holds the US registrations. ECO LLC is located at 8209 Hollister Avenue, Las Vegas, NV 89131. The NDC Labeler Code is 066916. All correspondence and enquiries regarding animal health products should be directed to the Princeton, NJ address.

Please do not hesitate to contact me if you have any questions or require additional information. Thank you.

Sincerely,



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