Related Determinations

EM; Docket ID FEMA–2010–0002]

[Docket No. FEMA–2010–N–0425]

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs). In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the regulations to remove portions reflecting approval of these NADAs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Withdrawal of Approval of New Animal Drug Applications; Chloramphenicol, Lincomycin, Pyrantel Tartrate, and Tylosin Phosphate and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs). In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the regulations to remove portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective September 24, 2010.

FOR FURTHER INFORMATION CONTACT: John Bartkowski, Center for Veterinary Medicine (HVY–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, email: john.bartkowski@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611; International Nutrition, Inc., 7706 "I" Plaza, Omaha, NE 68127; and Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001 have requested that FDA withdraw approval of the four NADAs listed in table 1 because they are no longer manufactured or marketed:

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>NADA Number Product (Established Name of Drug)</th>
<th>21 CFR Cite (Sponsor’s Drug Labeler Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611</td>
<td>NADA 65–137 AMPHICOL–V Capsules (chloramphenicol)</td>
<td>§ 520.390b (058034)</td>
</tr>
<tr>
<td>International Nutrition, Inc., 7706 “I” Plaza, Omaha, NE 68127</td>
<td>NADA 121–337 INI Swine Ban-Wormer B–9.6 BA. (pyrantel tartrate)</td>
<td>§ 558.485 (043733)</td>
</tr>
<tr>
<td>International Nutrition, Inc., 7706 “I” Plaza, Omaha, NE 68127</td>
<td>NADA 132–923 LINCO 8/LINCO 20 (lincomycin)</td>
<td>§ 558.325 (043733)</td>
</tr>
<tr>
<td>Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001</td>
<td>NADA 138–342 TYLAN 5 Sulfa-G Premix (tylosin and sulfamethazine)</td>
<td>§ 558.630 (030841)</td>
</tr>
</tbody>
</table>

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with §514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 65–137, 121–337, 132–923, and 138–342, and all supplements and amendments thereto, is hereby withdrawn, effective September 24, 2010.

In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.


Richard U. Rodriguez,
Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

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