DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0151]

Withdrawal of Approval of New Animal Drug Applications; Chorionic Gonadotropin; Cuprimyxin; Diethylcarbamazine; Levamisole; Nitrofurazone; Phenylbutazone; Pyrantel; Tylosin; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 13 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 April 11, 2011.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, e-mail: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors of the 13 approved NADAs listed in table 1 have requested that FDA withdraw approval because the products are no longer manufactured or marketed.

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>NADA No. Product (Established Name of Drug)</th>
<th>21 CFR Section Affected (Sponsor’s Drug Labeler Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298.</td>
<td>NADA 093–029 .................................................</td>
<td>524.520 (063238)</td>
</tr>
<tr>
<td>Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.</td>
<td>UNITOP Cream .................................................</td>
<td>524.520 (063238)</td>
</tr>
<tr>
<td>Abris Pharmaceutical Products, Division of Abris Bioscience, 6133 River Rd., suite 500, Rosemont, IL 60018.</td>
<td>NADA 097–981 .................................................</td>
<td>558.630 (016968)</td>
</tr>
<tr>
<td>Furst-McNess Co., Freeport, IL 61032 ........................................</td>
<td>TYLAN 40 Sulfa-G Premix .......................................</td>
<td>522.1081 (063323)</td>
</tr>
<tr>
<td>Fort Dodge Animal Health, Division of Wyeth Holdings, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017.</td>
<td>TRAMISOL–10% Pig Wormer .....................................</td>
<td>Not codified (000856)</td>
</tr>
<tr>
<td>Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704.</td>
<td>NADA 101–905 .................................................</td>
<td>524.520 (063238)</td>
</tr>
<tr>
<td>Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704.</td>
<td>Mill Co-Medicator TY–10 ......................................</td>
<td>558.630 (017139)</td>
</tr>
<tr>
<td>Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.</td>
<td>NADA 102–824 .................................................</td>
<td>520.1720a (055246)</td>
</tr>
<tr>
<td>Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.</td>
<td>Phenylbutazone Tablets .......................................</td>
<td>520.1720a (055246)</td>
</tr>
<tr>
<td>Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.</td>
<td>DEC Tabs .......................................................</td>
<td>520.1720a (055246)</td>
</tr>
<tr>
<td>Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.</td>
<td>(diethylcarbamazine citrate) ...................................</td>
<td>520.1720a (055246)</td>
</tr>
<tr>
<td>Furst-McNess Co., Freeport, IL 61032 ........................................</td>
<td>NADA 106–487 ..................................................</td>
<td>520.622c (015579)</td>
</tr>
<tr>
<td>Furst-McNess Co., Freeport, IL 61032 ........................................</td>
<td>DEC Chewable Tabs .............................................</td>
<td>520.622c (015579)</td>
</tr>
<tr>
<td>Furst-McNess Co., Freeport, IL 61032 ........................................</td>
<td>(diethylcarbamazine citrate) ...................................</td>
<td>520.622c (015579)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>NADA 140–820 ..................................................</td>
<td>524.1580c (050749)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>TYLEN 40 Sulfa-G Premix .................................</td>
<td>558.485 (016968)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>(tylosin phosphate/sulfamethazine).........................</td>
<td>558.485 (016968)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>NADA 140–910 ..................................................</td>
<td>520.622a (015579)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>NFZ Wound Powder ............................................</td>
<td>520.622a (015579)</td>
</tr>
<tr>
<td>Hess &amp; Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.</td>
<td>(nitrofurazone) ...............................................</td>
<td>520.622a (015579)</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 93–029, 97–981, 100–840, 100–991, 101–079, 101–905, 101–906, 102–824, 108–487, 108–863, 140–820, 140–825, and 140–910, and all supplements and amendments thereto, is hereby withdrawn, effective April 11, 2011.
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.

Dated: March 25, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Epidemiology.

Date: April 25, 2011.

Time: 11 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, krishnak@csr.nih.gov.

Name of Committee: Binational Research Program; Member Conflict: Endocrinology and Metabolism.

Dated: March 25, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Member Conflict: Endocrinology and Metabolism.

Date: April 25, 2011.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Erica L. Brown, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2639, ebrown@niaid.nih.gov

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Next Generation PrEP.

Date: April 29, 2011.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Roberta Binder, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892–7616, 301–496–7986, rbindner@niaid.nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health & Human Development; Planning and Implementation Grants.

Dated: March 25, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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