RECORD SOURCE CATEGORIES:

Vital status information is obtained from Federal, State and local governments and other available sources selected from those listed in Appendix I. Information is obtained directly from the individual and employer records, whenever possible.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—Potential Sources for Determination of Health Status, Vital Status and/or Last Known Address

Military records
Appropriate State Motor Vehicle Registration Departments
Appropriate State Driver's License Departments
Appropriate State Government Division of: Assistance Payments (Welfare), Social Services, Medical Services, Food Stamp Program, Child Support, Board of Corrections, Aging, Indian Affairs, Worker's Compensation, Disability Insurance
Retail Credit Association follow-up
Veterans Administration files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life insurance companies
Railroad Retirement Board
Area nursing homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service
National Death Index
Health Care Finance Administration
Pension Benefit Guarantee Corporation
State Disease Registries

[FR Doc. 01–20478 Filed 8–14–01; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0287]

EVSCO Pharmaceuticals, an Affiliate of IGI, Inc.; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) held by EVSCO Pharmaceuticals, an Affiliate of IGI, Inc. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove the portions reflecting approval of the NADAs because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective August 27, 2001.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5593.

SUPPLEMENTARY INFORMATION: EVSCO Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310, has requested that FDA withdraw approval of NADA 32–984 for Cerumite (chloramphenicol, prednisolone, tetracaine, and squalane) topical suspension, and NADA 55–005 for Liquichlor with Cerumene (squalane, pyrethrins, and piperonyl butoxide) topical suspension because the products are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 32–984 and 55–005 and all supplements and amendments are withdrawn effective August 27, 2001.

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

Dated: August 6, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–20574 Filed 8–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0316]

Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an inspection guidance entitled ''Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients.'' This guidance will assist FDA investigators and inspectors in evaluating conditions that may result in the introduction of undeclared allergens in foods.

DATES: Submit written or electronic comments on this guide at any time.

ADDRESSES: Submit written requests for single copies of the inspection guidance entitled ''Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients'' to the Director, Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–6919. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guide.

Submit written comments concerning the guidance to the Dockets Management Branch (HFS–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Technical questions concerning food allergens: Kathy Gombas, Office of Field Programs (HFS–615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136.

Questions concerning regulatory procedures: Barbara Marcelletti, Office of Regional Operations (HFC–130), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5635, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed an inspection guidance identifying the following problem areas in the manufacture of foods that may result in undeclared food allergens: (1) Products that contain one or more allergenic ingredients, but the label does not declare the ingredient in the ingredient label; (2) products that become contaminated with an allergenic ingredient due to the firm's failure to exercise adequate control procedures; (3) products that are contaminated with

an allergenic ingredient due to the nature of the product or the process; (4) products that contain a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor; and (5) products that contain a processing aid that has an allergenic component, but the label does not declare it. FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90 percent of all food allergies: Peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is reference material for investigators and other FDA personnel. The guidance does not bind FDA and does not confer any rights, privileges, benefits, or immunities for or on any person(s). An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both. The guidance will help ensure more effective inspections and further FDA's efforts to prevent potential serious allergic reactions in sensitive individuals resulting from undeclared allergens in food. FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115). Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability if the guidance is revised.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments regarding the guide. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the guide and may be accessed at http://www.fda.gov/ora under ''Inspectional References.''

Dated: July 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20481 Filed 8–10–01; 11:07 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0311]

Medical Devices: Draft Guidance on ''Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA.'' This draft guidance document will serve as the special control for reclassification of the endolymphatic shunt tube with valve device from class III to class II. The draft guidance document outlines the technical areas to address in order to control the risks associated with the endolymphatic shunt tube with valve and to provide for a timely premarket notification (510(k)) review. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by November 13, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing you request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: James K. Kane, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA.'' The draft guidance document is the special control guidance for the endolymphatic shunt tube with valve. Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the device from class III to class II when it is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's Disease. FDA intends that this draft guidance document, if finalized, will serve as the special control for the endolymphatic shunt tube with valve. If finalized, the guidance will supersede the guidance document entitled ''Guidance for the Technical Content of a Premarket Approval Application for an Endolymphatic Shunt Tube With Valve'' that FDA issued in April 1990.

II. Significance of Guidance

The draft guidance represents the agency's current thinking on the endolymphatic shunt tube with valve. 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 applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH