ATTACHMENT 7

FEDERAL REGISTER NOTICE
DECEMBER 3, 1985, VOLUME 50, P. 49617-49619

Transaction	Waiting period terminated effective
86-0164—Cibrel Brothers, Inc.'s proposed acquisition of voting securities of Schenley & Myers do Brasil Cigarros Ltda. (Grand Metropolitan PLC, UPE).	Dec.
86-0176—Coit Industries, Inc.'s proposed acquisition of voting securities of Alcar, Inc.	Dec.
86-0181—Coit Industries, Inc.'s proposed acquisition of voting securities of Alcar, Inc.	Dec.
86-0185—Proposed consolidation of Intel Communication Services, Inc. and Lenstel Corporation.	Dec.
86-0191—Melvyn J. Goodman's proposed acquisition of voting securities of Alex Corp.	Dec.
86-0192—Philip D. Goodman's proposed acquisition of voting securities of Alex Corp.	Dec.
86-0193—Kansas City Southern Industries, Inc.'s proposed acquisition of voting securities of Alex Corp.	Dec.
86-0194—Michael P. Richer's proposed acquisition of voting securities of Alex Corp.	Dec.
86-0195—Bennett S. LeBow's proposed acquisition of voting securities of the Wild Foods, Inc.	Nov. 14, 1985.
86-0226—Eastern Gas and Fuel Associates's proposed acquisition of voting securities of Nicor Mining, Inc. and Cameo Minerals, Inc. (Nicor, Inc., UPE).	Dec.
86-0227—Nicor Inc.'s proposed acquisition of assets of Powderhorn Properties Co. and voting securities of Beacon Coal Corp.	Dec.
86-0157—Hillenbrand Industries, Inc.'s proposed acquisition of voting securities and assets of Support Systems International.	Nov. 18, 1985.

For further information contact: Sandra M. Peay, Legal Technician, Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580, (202) 523-3894.

By direction of the Commission.

Emily H. Rock,

Secretary.

[FR Doc. 85-28823 Filed 12-2-85; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in Cigarettes

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice implements the requirement of the Federal Cigarette Labeling and Advertising Act that each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of cigarettes.

DATES: The lists are required to be provided to HHS April 2, 1986, and annually thereafter by December 31, beginning with December 31, 1986.

ADDRESS: The list shall be submitted to: Director, Office on Smoking and Health, Park Building, Room 1-10, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Donald R. Shopland, Acting Director, Office on Smoking and Health, (301) 443-1575.

SUPPLEMENTARY INFORMATION: Section 5(a) of Pub. L. 98-474 added a new section 7 to the Federal Cigarette Labeling and Advertising Act. That Section requires manufacturers, importers, and packagers of cigarettes to provide the Secretary of HHS annually with a list of all ingredients added to tobacco in the manufacture of cigarettes. The list shall not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients.

The list shall be provided reporting each ingredient by chemical name and chemical abstract service (CAS) registry number. A person or group of persons required to provide a list may designate an individual or entity to provide the list on their behalf. In such case, the designated individual or entity shall identify the person or group of persons on whose behalf the list is submitted.

In accordance with section 7, procedures for assuring the confidentiality of the information are available. A copy of these procedures may be obtained by written request to the address stated above. The information submitted will be treated as trade secret or confidential information subject to 5 U.S.C. 552(b)(4) and 18 U.S.C. 1905. Access to the information will be limited to those authorized by the Secretary in carrying out their official duties and, upon their request, to duly authorize committees or subcommittees of the Congress.

Dated November 4, 1985.

James O. Mason,

Acting Assistant Secretary for Health.

Dated November 25, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

Guidelines To Control and Protect Documents That Contain Privileged Information Obtained in Accordance With Sec. 5(a) of Pub. L. 98-474

1. Purpose

This guide establishes minimum requirements to control and protect those documents that contain privileged information. Its objective is to establish individual responsibility for the accountability and protection of privileged information provided to the Secretary, Department of Health and Human Services, specifically that information on the ingredients added to tobacco in the manufacture of cigarettes as called for under Pub. L. 98-474. This document is directed at setting forth specific conditions governing access to privileged information, including trade secret data.

2. Policy

The Department of Health and Human Services recognizes that trust placed in it under the requirements of the Federal Statutes with respect to safeguarding privileged information. Employees of the Department of Health and Human Services shall take such action as may be necessary to preclude a breach of this trust. Privileged information shall be released only to employees of the Department as described herein, unless otherwise authorized by law or by the source of the information. Any Freedom of Information Act request for information obtained by the Department under section 5(a) of Pub. L. 98-474 shall be referred to the Freedom of Information Officer of the Public Health Service. In accordance with the provisions of 5 U.S.C. 552(b)(3) and 552(b)(4), 18 U.S.C. 1905, section 7(b)(2)(A) of Pub. L. 98-474, and 42 CFR 5.71, the Freedom of Information Officer shall deny any such requests. Any request for such information that is not submitted under the Freedom of Information Act shall be referred to the Director of the Office on Smoking and Health. With the exception of duly authorized request by a committee or subcommitte of Congress made in accordance with section 7(b)(2)(B) of Pub. L. 98-474, any such request shall be denied.

3. Statutory Requirements

Statutory requirements for safeguarding privileged information entrusted to the Department of Health and Human Services are contained in the following:

a. Section 7(b)(2)(A) of the Federal Cigarette Labeling and Advertising Act.

b. Section 1905, Title 18 U.S.C. Crimes and Criminal Procedure (18 U.S.C. 1905).

c. Section 552(b)(4), Title 5, U.S.C.

4. Definitions

a. *Document Control Officer.* That individual who has been designated in writing as having the responsibility for the organization's secret document control. The Document Control Officer shall be the Director, Office on Smoking and Health.

Signed: _____
Date: _____
Witnessed by: _____
Date: _____

Attachment B—Receipt for Confidential Information on the Ingredients Added to Tobacco in the Manufacture of Cigarettes

To: Director, Office on Smoking and Health, Office of the Assistant Secretary for Health, Rockville, Maryland 20857

From:

Receipt of the following privileged information is hereby acknowledged:

File #: _____
Description of Information: _____
Anticipated Date of Return: _____
Date: _____
Signature: _____

Attachment C—Authority To Remove Confidential Information on the Ingredients Added to Tobacco in the Manufacture of Cigarettes

_____ (name) of _____ (government agency or office) is hereby granted the authority to have the following privileged information in his/her personal possession from _____ (hours), _____ (date) to _____ (hours), _____ (date).

Described Privileged Information:
Document Number:
Title:

This information will be used for:

Authorized by: _____
Director, Office on Smoking and Health
Date: _____

[FR Doc. 85-28715 Filed 12-2-85; 8:45 am]
BILLING CODE 4160-17-M

Food and Drug Administration

Midicel® Tablets; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) sponsored by Parke-Davis covering use of Midicel® Tablets (sulfamethoxypyridazine) in treating dogs and cats for sulfa-susceptible, gram-positive and gram-negative, bacterial infections. The sponsor requested the withdrawal of approval.

EFFECTIVE DATE: December 13, 1985.

FOR FURTHER INFORMATION CONTACT: John K. Augsburg, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950, is sponsor of NADA 12-821 for use of Midicel® Tablets (sulfamethoxypyridazine) in treating dogs and cats for sulfa-susceptible, gram-positive and gram-negative, bacterial injections.

The application was originally approved February 8, 1963. In a letter dated August 7, 1985, the firm requested withdrawal of approval of the NADA because the drug is no longer being marketed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e)) and 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 NADA 12-821 for Midicel® Tablets (sulfamethoxypyridazine) is hereby withdrawn, effective December 13, 1985.

In a final rule published elsewhere in this issue of the Federal Register, the regulation reflecting this approval is removed.

Dated: November 25, 1985.

Gerald B. Guest,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 85-28834 Filed 12-2-85; 8:45 am]
BILLING CODE 4160-01-M

Vortech Pharmaceuticals, Ltd.; Dichlorophene and Toluene Capsules; Withdrawal of Approval

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) sponsored by Vortech Pharmaceuticals, Ltd. (formerly sponsored by North American Pharmacal), for dichlorophene and toluene capsules. The firm requested the withdrawal of approval.

EFFECTIVE DATE: December 13, 1985.

FOR FURTHER INFORMATION CONTACT: John Augsburg, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Vortech Pharmaceuticals, Ltd., P.O. Box 189, Dearborn, MI 48121, informed FDA, by letter dated July 26, 1983, that it had purchased the assets of North American Pharmacal, 8851 Chase Rd., Dearborn, MI 48128, in June 1982. At the time it was purchased, North American Pharmacal was the sponsor of NADA 110-736 for PETAVERM Capsules (dichlorophene and toluene) labeled as an anthelmintic for dogs and cats.

Vortech Pharmaceuticals, Ltd., stated, by letter dated July 8, 1985, that PETAVERM has never been brought to market and is not in use, and the company requested that the drug be withdrawn.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and 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 NADA 110-736 and all supplements thereto is hereby withdrawn, effective December 13, 1985.

In a final rule published elsewhere in this issue of the Federal Register, FDA is removing that portion of the regulations that reflects this NADA approval.

Dated: November 25, 1985.

Gerald B. Guest,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 85-28832 Filed 12-2-85; 8:45 am]
BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. I-85-138]

Intended Environmental Impact Statement

The Department of Housing and Urban Development gives notice that an Environmental Impact Statement (EIS) is intended to be prepared by the cities of Auburn Hills and Rochester Hills, Oakland County, Michigan, for the Oakland Technology Park under the HUD programs as described in the appendix of the Notice. This notice is required by the Council on Environmental Quality under its rule (40 CFR Part 1500).

Interested individuals, governmental agencies, and private organizations are invited to submit information and comments concerning the particular project to the specific person or address indicated in the appropriate part of the appendix.

Particularly solicited is information on reports or other environmental studies planned or completed in the project

ATTACHMENT 8

REQUEST FOR ADDITIONAL INFORMATION FROM MANUFACTURERS, PACKAGERS AND IMPORTERS OF TOBACCO PRODUCTS

Form Approved
OMB# 0920-0210
Expiration Date: 08/31/2007

«Name»
«Company»
«Address_1»
«Address_2»
«City_State_Zip»

Dear «Salutation»:

This letter is to notify you that the Centers for Disease Control and Prevention (CDC) has begun processing the Ingredient Report recently submitted by you on «date», on behalf of «Company». As you know, 15 U.S.C. §4403(a)(A) of the Comprehensive Smokeless Tobacco Health Education Act provides in part that each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Department of Health and Human Services with a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products as well as a specification of the quantity of nicotine contained in each product.

Based on an initial review of the submissions, CDC has noted several errors, which are summarized in the attached document. Please correct these errors and provide a written update within 60 business days. Upon receipt of your corrected Ingredient Report, CDC will complete its review of your submission and provide a final determination regarding compliance.

If you require additional assistance please contact Ruth L. Hayes, (770) 488-5743.

Sincerely yours,

Matthew T. McKenna, MD, MPH
Director
Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion

Enclosure: (1)

ATTACHMENT 9

FEDERAL REGISTER NOTICE
NOVEMBER 8, 1994, VOLUME 59, P. 55669-55670

(Federal Register: February 1, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice Regarding Requirement for Submission of List of Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco Products**

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice implements the requirement of the Comprehensive **Smokeless Tobacco** Health Education Act of 1986 (Public Law 99-252) that each person who manufactures, packages, or imports **smokeless tobacco** shall provide the Secretary of Health and Human Services (HHS) annually with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. (This statute also requires reporting to HHS the nicotine content of **smokeless tobacco** products. The nicotine reporting requirement will be implemented at a later date.)

DATES: The first ingredient list is due on April 4, 1994, and shall identify all ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products marketed on December 31, 1993. Beginning in 1994 and each subsequent calendar year, the ingredient list will be due on December 31, and shall identify any changes in the ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products at any time during the previous twelve months.

ADDRESSES: The list shall be submitted to: Michael P. Eriksen, Sc.D., Director,Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Atlanta, GA 30341-3724.

FOR FURTHER INFORMATION CONTACT: Michael P. Eriksen, Sc.D., Director, Office on Smoking and Health, (404) 488-5701.

SUPPLEMENTARY INFORMATION: Section 4(a) of Public Law 99-252 (15 U.S.C. 4403(a)) requires manufacturers, packagers, and importers of **smokeless tobacco** products to provide the Secretary of HHS annually with a list of all ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products. This statute also stipulates that the list need not identify the company which uses the ingredients or the brand of **smokeless tobacco** which contains the ingredients.

The implementation procedures HHS has established for submitting the ingredient information require respondents to report each ingredient by chemical name and Chemical Abstract Service (CAS) Registry Number. This format for reporting ingredients is consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products, including cigarettes.

The statute permits a person or group of persons required to submit an ingredient list to HHS to designate an individual or entity to provide information on their behalf. In such case, HHS

procedures require the designated individual or entity to identify for HHS the person or group of persons on whose behalf the ingredient list is being submitted.

HHS has established strict procedures for assuring the confidentiality of the information submitted in accordance with section 4 (b) (2) (C) of Public Law 99-252 (15 U.S.C. 4403 (b) (2) (c)). The information will be treated as trade secret or confidential information subject to 5 U.S.C. 552 (b) (4). Access to the information will be limited to those authorized by the Secretary in carrying out their official duties and to duly-authorized committees or subcommittees of the Congress that submit a written request for the information.

Information Collection Provisions:

This Notice contains information collections which have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 and assigned the control number 0920-0338. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and record keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco** Products.

Description: The Comprehensive **Smokeless Tobacco** Health Education Act of 1986 requires HHS to collect this information. HHS is authorized to conduct research on the potential health effects of the ingredients, and to report to the Congress as appropriate.

Description of Respondents: Businesses or Other For-Profit Organizations.

Estimated Annual Reporting and Recordkeeping Burden: The Office on Smoking and Health (OSH) contacted five **smokeless tobacco** manufacturers, through the law firm of Patton, Boggs and Blow, which will submit ingredient information in order to estimate the annualized cost for reporting ingredient information to the Department of Health and Human Services. The estimated average cost to industry for this three year period is $4,314. This is based on an annualized estimated cost of $1,438 per company with an annual estimated cost range of $250 to $3500 per company per year. The estimated cost to the government for this collection and storage over a three year period is $18,000.00. This cost is based on an annualized estimated cost of $6,000.00 for collection and storage.

There are 11 manufacturers, packagers, and importers of **smokeless tobacco** products in the U.S. In November 1992, OSH contacted five companies, through the law firm of Patton, Boggs and Blow, which will submit ingredient information to the Department of Health and Human Services, regarding the estimated response burden to the industry. Patton, Boggs and Blow reported that the annual response burden for each company it represents ranges from 4 to 30 manhours, with an average burden of 15 hours per company.

Dated: January 25, 1994.

Walter R. Dowdle,

Deputy Director, Centers for Disease Control and Prevention (CDC).