clearly demonstrates the Tribe's support of the project and the Tribe's understanding that the other applicant's project supplants the Tribe's authority to submit an application for the duration of the approved grant period.

The application's Form 424 must be signed by the applicant's representative authorized to act with full authority on behalf of the applicant.

The Administration for Native Americans recommends that the pages of the application be numbered sequentially and that a table of contents be provided. Simple tabbing of the sections of the application is also helpful to the reviewers.

An application with an original signature and two additional copies are required. The Cover Page (included in the Kit) should be the first page of an application, followed by the one-page abstract.

The Approach page (Section B of the ANA Program Narrative) for each Objective Work Plan proposed should be of sufficient detail to become a monthly staff guide for project responsibilities if the applicant is funded.

Line 15a of the Form 424 must specify the Federal funds requested for the Budget Period. The Administration for Native Americans will critically evaluate applications in which the acquisition of equipment is a major component of the Federal share of the budget. ''Equipment is tangible, non-expendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.'' During negotiation, such expenditures may be deleted from the budget of an otherwise approved application, if not fully justified by the applicant and not deemed appropriate to the needs of the project by ANA.

Applicants are encouraged to request a legibly dated receipt from a commercial carrier or U.S. Postal Service as proof of timely mailing.

3. Projects or Activities That Generally Will Not Meet The Purposes of This Announcement

The support of on-going social service delivery programs or the expansion, or continuation, of existing social service delivery programs.

Core administration functions, or other activities, which essentially support only the applicant's on-going administrative functions. Project goals, which are not responsive to this program announcement.

Proposals from consortia of Tribes that are not specific with regard to support from, and roles of, member Tribes.

Projects that will not be completed by the end of the project period.

ANA will not fund the purchase of real estate (see 45 CFR 1336.50 (e)) or construction.

Projects originated and designed by consultants who provide a major role for themselves in the proposed project and are not members of the applicant organization, Tribe or village.

H. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995, Pub. L. 104–13, the Department is required to submit to the Office of Management and Budget (OMB) for review and approval any reporting and recordkeeping requirements in regulations including program announcements. Information collection through this Program Announcement, including the program narrative statement, are approved by the OMB under control number 0980–0204, which expires April 30, 2003.

I. Receipt of Applications

The closing date for the submission of applications is [30 days from the date of publication in the **Federal Register**]. Applications postmarked after the closing date will be classified as late.

1. Deadline

Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW, Mail Stop 6C–462, Washington, DC 20447.

Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Applications hand carried by applicants, applicant couriers, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, Monday through Friday (excluding Federal holidays), between the hours of 8 a.m. and 4:30 p.m., at: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, SW., Washington, DC 20024.

(Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

2. Late Applications

Applications, which do not meet the criteria above, are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

3. Extension of Deadlines

The Administration for Children and Families may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc., widespread disruption of the mails, or when it is anticipated that many of the applications will come from rural or remote areas. However, if ACF does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicant.

(Catalog of Federal Domestic Assistance Program Number: 93.612 Native American programs)

Dated: June 30, 2000.

Gary Mounts,

Acting Commissioner, Administration for Native Americans.

[FR Doc. 00–17204 Filed 7–6–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 95F–0092, 95F–0129, 95F–0130, 97F–0175, 97F–0406, 97F–0414, 98F–0053, 98F–0058, 98F–0436, 98F–0714, 98F–1021, 99F–0804, 99F–1419, 99F–2080, 99F–2552, 99F–2908, 99F–2997, 99F–2998, and 99F–4373]

Withdrawal of Food Additive Petitions Subsequently Converted to Food Contact Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice to a future filing of 19 food additive petitions proposing that the food additive regulations be amended to provide for the safe use of certain new food additives. The petitioners subsequently requested that their

petitions be converted to food-contact notifications for review under the agency's new premarket notification (PMN) program for food-contact substances. The requested uses are now the subjects of effective notifications.

FOR FURTHER INFORMATION CONTACT: Mark Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In notices published in the **Federal Register** (FR), on the dates indicated in the table below, FDA announced the filing of 19 food additive petitions. These petitions proposed to amend the food additive regulations in the sections listed in the table to provide for the safe use of the listed substances intended for use in food-contact articles. Since publication of these filing notices, the petitioners have requested that their respective petitions be converted to food-contact notifications for review under the agency's new PMN process for food-contact substances and that their petitions be withdrawn when the corresponding notifications become effective. These petitions were converted to notifications and subsequently reviewed under the the PMN process. The requested uses are now the subjects of effective notifications. The corresponding food additive petitions are now withdrawn without prejudice to a future filing (21 CFR 171.7).

TABLE 1

FAP No.[1] and Docket No.	FCN No.[2]	FR Citation and Date	Company	Section/Part	Additive	Use
9B4662, 99F–1419	1	64 FR 28000, May 24, 1999	Milliken & Co. c/o Keller & Heckman.	Proposed new section in part 178.	Silver sodium hydrogen zirconium phosphate	Antimicrobial for polymers for food packaging.
8B4632, 98F–1021	3	63 FR 67075, Dec. 4,1998	Rohm and Haas Co. c/o Keller & Heckman.	176.170	Styrene acrylic copolymers	Paper and paperboard coating.
8B4564, 98F–0053	5	63 FR 5808, Feb. 4, 1998	Currently, BP Amoco Chemicals, Inc.	177.1480	Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.	Beverage containers.
5B4455, 95F–0092	4	60 FR 22400, May 5, 1995	Currently, BP Amoco Chemicals, Inc.	177.1630	Ethylene terephthalate-isophthalate copolymers with 83–97 weight percent ethylene terephthalate units.	Components of food-contact articles.
5B4450, 95F–0130	8	60 FR 32526, June 22, 1995	Shell Chemicals Co.	177.1630	Ethylene terephthalate polymers containing less than 50 weight percent of polymer units derived from ethylene 2,6-naphthalene.	Components of food-contact articles.
5B4451, 95F–0129	9	60 FR 32159, June 20, 1995	Shell Chemicals Co.	Proposed new section in part 177.	Poly(oxy-1,2-ethanediyloxycarbonyl-2,6-napthalenediylcarbonyl) polymer and the copolymer poly(oxy-1,2-ethanediyloxy carbonyl-2,6-naphthalenediylcarbonyl) with ethylene terephthalate.	Components of food-contact articles.
8B4582, 98F–0058	10	63 FR 6571, Feb. 9, 1998	Currently, Sekisui Plastics Co., Ltd. c/o Ungaretti & Harris.	177.1630	Pyromellitic dianhydride	Modifier in ethylene terephthalate. copolymers.
7B4558, 97F–0406	12	62 FR 51873, Oct. 3, 1997	Sveriges Starkelseproducenter c/o Kirschman Assoc.	178.3520	Industrial starch modified with up to 21 percent 2,3-epoxypropyltrimethyl ammonium chloride.	Component of food-contact articles.
9B4685, 99F–2908	19	64 FR 47843, Sept. 1, 1999	The Goodyear Tire & Rubber Co. c/o Keller & Heckman.	175.300	Piperylene/2-methyl-2-butene/ alpha-methylstyrene terpolymer.	Can end cement.
9B4645, 99F–0804	11	64 FR 19182, Apr. 19, 1999	Rohm and Haas Co.	176.170 and 176.300.	4,5-Dichloro-2-n-octyl 3 (2H)-isothiazolone	Preservative and slimicide for paper and paperboard.

TABLE 1—Continued

FAP No.[1] and Docket No.	FCN No.[2]	FR Citation and Date	Company	Section/Part	Additive	Use
7B4554, 97F–0414	15	62 FR 52137, Oct. 6, 1997	Stilbene Whitening Agent Task Force c/o Keller & Heckman.	176.170	Benzenesulfonic acid, 2,2-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl)-amino]-6-[(4-sulfonphenyl)amino]-1,3,5-triazin-2-yl]amino]-,tetrasodium salt.	Optical brightner in paper and paperboard.
8B4617, 98F–0714	20	63 FR 46226, Aug. 31, 1998	Asahi Denka Kogyo, K.K. c/o Japan Technical Information Center, Inc.	178.2010	2,2′-methylenebis(4,6-di-tert-butylphenyl)2-ethylhexyl phosphite.	Antioxidant and/or stabilizer in linear low density polyethylene.
8B4599, 98F–0436	21	63 FR 34188, June 23, 1998	Asahi Denka Kogyo, K.K. c/o Japan Technical Information Center, Inc.	178.2010	2,2′-methylenebis(4,6-di-tert-butylphenyl)2 -ethylhexyl phosphite.	Antioxidant and/or stabilizer in high density polyethylene.
9B4679, 99F–2552	22	64 FR 43189, Aug. 9, 1999	Asahi Denka Kogyo, K.K. c/o Japan Technical Information Center, Inc.	178.2010	Phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-tert-butyl-4-methylphenyl) ester.	Antioxidant and/or stabilizer in polyolefins.
9B4667, 99F–2080	23	64 FR 36361, July 6, 1999	Engelhard Corp.	178.3297	Solution of 1-naphthalenesulfonic acid, 12-[(2-hydroxy-6-sulfo-1-naphthalenyl)azo]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[4-chloro-5-ethyl- 2-sulfophenyl)azo]-6-hydroxy-, strontium salt (1:1) (C.I. Pigment Red 277).	Colorant for polymers.
7A4541, 97F–0175	30	62 FR 25633, May 9, 1997	Currently, Betz Dearborn c/o Keller and Heckman	173.310	Copolymer of acrylic acid and polyethylen eglycol allyl ether.	Boiler water additive.
9B4694, 99F–2998	29	64 FR 48654, Sept. 7, 1999	Asahi Denka Kogyo, K.K.	178.2010	Tridecanol phosphite condensation product with butylidenebis[2-(1,1-dimethylethyl)- 5-methyl-4,1-phenylene].	Antioxidant and/or stabilizer in styrene-isoprene-styrene copolymer to be used as a component of pressure-sensitive adhesives.
9B4691, 99F–2997	25	64 FR 49496, Sept. 13, 1999	Engelhard Corp.	178.3297	1-naphthelenesulfonic acid, 2-[(4,5-dihydro-3-methyl-5-oxo-1-(3-Sulfophenyl)-1H-pyrazol-4- yl)azo]-, strontium and calcium salt (1:1)(C.I. Pigment 209 and C.I. Pigment 209:1).	Colorant for polymers.
9B4698, 99F–4373	26	64 FR 58070, Oct. 28, 1999	Engelhard Corp.	178.3297	A solid solution of 2-naphthalene sulfonic acid, 15-[(5-chloro-4-methyl-2-sulfophenyl)azo]- 6-hydroxy]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[(4-chloro-5-ethyl-2-sulfonphenyl)azo]-6- hydroxy]-,strontium salt (1:1)(C.I. Pigment Red 276).	Colorant for polymers.

[1] Food additive petition number.
[2] Food-contact notification number.

Dated: June 28, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for food Safety and Applied Nutrition.

[FR Doc. 00–17199 Filed 7–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 83N–0118; DESI 6514]

Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Drug Efficacy Study Implementation; Caramiphen Edisylate; Final Actions on Supplemental New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) refuses to approve supplemental new drug applications (NDA's) for Tuss-Ornade Spansules and Liquid containing caramiphen edisylate and phenylpropanolamine hydrochloride. The basis for FDA's refusal to approve these products is that there is a lack of substantial evidence that caramiphen edisylate is effective.

DATES: Effective July 7, 2000.

ADDRESSES: Requests for applicability of this notice to a specific product should be identified with Docket No. 83N–0118 and reference number DESI 6514 and directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 9, 1973 (38 FR 4006), FDA classified the following drug products as less than effective for their labeled indications:

1. NDA 12–903; Tuss-Ornade Spansules containing caramiphen edisylate 20 milligrams (mg), chlorpheniramine maleate 8 mg, phenylpropanolamine hydrochloride 50 mg, and isopropamide iodide 2.5 mg; SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101–7929 (SmithKline).

2. NDA 13–068; Tuss-Ornade Liquid containing caramiphen edisylate 5 mg, chlorpheniramine maleate 2 mg, phenylpropanolamine hydrochloride 15 mg, and isopropamide iodide 0.75 mg; SmithKline.

In a notice published in the **Federal Register** of December 14, 1973 (38 FR 34481), FDA granted a temporary exemption from the time limits established for completing certain phases of the drug efficacy study implementation (DESI) program, for certain oral prescription drugs offered for relief of cough, cold, allergy, and related symptoms, including the aforementioned products. The exemption was granted because of the close relationship between drugs sold over the counter (OTC)—and thus subject to the ongoing OTC drug review (21 CFR part 330)—and prescription drugs offered for relief of cough, cold, allergies, and related symptoms.

In 1980 SmithKline submitted supplements proposing to reformulate the products listed above and marketed the following reformulated products pending a final determination of effectiveness:

1. NDA 12–903; caramiphen edisylate 40 mg and phenylpropanolamine hydrochloride 25 mg.

2. NDA 13–068; caramiphen edisylate 6.7 mg and phenylpropanolamine hydrochloride 12.5 mg.

In 1976 the OTC drug review panel for cold, cough, allergy, bronchodilator, and antiasthmatic drugs concluded that there were no well-controlled, objective, clinical studies documenting the effectiveness of caramiphen edisylate as an antitussive (41 FR 38312, September 9, 1976). The OTC monograph on antitussives was finalized in 1987 (52 FR 30042 at 30054, August 12, 1987).

Because of the lack of evidence that caramiphen edisylate is an effective antitussive, the Director of what was then the National Center for Drugs and Biologics concluded that there was a lack of substantial evidence that Tuss-Ornade Spansules and Liquid, either as previously formulated or as proposed for reformulation, would have all the effects they purported or were represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. The Director issued a notice of opportunity for hearing on two proposals: (1) To withdraw approval of the original formulations of Tuss-Ornade Spansules and Liquid, and (2) to refuse approval of the supplemental reformulations of the same products (48 FR 40322, September 6, 1983).

Neither SmithKline nor any other interested party requested a hearing on the proposal to withdraw approval of the original formulations of Tuss-Ornade Spansules and Liquid; therefore, approval of the old formulations was withdrawn (49 FR 10707, March 22, 1984). However, in response to the agency's September 6, 1983, proposal to refuse to approve the reformulated products, SmithKline and National Pharmaceutical Manufacturing Company (National) requested hearings. SmithKline submitted data and information in support of its hearing request.

FDA has reviewed these data and determined that there is not substantial evidence of the effectiveness of caramiphen edisylate. SmithKline and National no longer market the products named in their 1983 hearing requests and have withdrawn those hearing requests.

This notice applies to any drug product that is identical, related, or similar to the products named above and is not the subject of an approved NDA (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and under the authority delegated to her (21 CFR 5.70 and 5.82) finds that, on the basis of new information before her with respect to Tuss-Ornade Spansules and Liquid, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the products as proposed for reformulation will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approvals and all the amendments and supplements thereto of NDA 12–903 and NDA 13–068 are withdrawn and refused effective July 7, 2000. Shipment in interstate commerce of the products listed above or of any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: June 20, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–17197 Filed 7–6–00; 8:45 am]

BILLING CODE 4160–01–F