families. Families that apply (or reapply) for subsidies and are determined to be eligible under current rules will be randomly assigned to the experimental co-payment schedule or the existing schedule. (Families with co-payments from the experimental schedule will either pay the same amount, or less, than families whose co-payments are calculated using the existing schedule.) Families will retain the same co-payment schedule for two years, provided they continue to be eligible for subsidies. Outcomes will be measured through analysis of administrative data and periodic interviews with parents.

Massachusetts. In Massachusetts, the study is an experimental test of the effectiveness of a developmental curriculum implemented in family child care homes. Family child care providers who serve subsidized and other low-income children and are linked to family child care networks will be randomly assigned to a treatment or control group. Providers in the treatment group will use the developmental curriculum and be trained through regular visits to the home by specially trained mentors. These providers will receive materials to use with children from 0 to 5 years of age. Providers in the control group will receive the more general technical assistance and support visits that they currently receive. Impacts on provider behavior and the home environment will be measured through direct observations in the homes. Child assessments will be conducted through provider reports for the younger children and through standardized tests for children 30 months and older.

Respondents: Illinois. Parents who apply (or reapply) for subsidies and are eligible and agree to be in the study will be interviewed by telephone up to three times in the 24 months after they enter the study.

Washington State. Parents who apply (or reapply) for subsidies and are eligible and agree to be in the study will be interviewed by telephone up to three times over the 24 months of the study. Approximately 30 state employees working at the Department of Health and Human Services in the Division of Child Care and Early Learning or the Division of Community Service will be interviewed as part of the implementation study.

Massachusetts. Children will be assessed 7 months after implementing the curriculum, after 11 months, and after 23 months. Providers will be asked to respond to a brief survey 7 and 23 months after the study begins.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Illinois parent survey	5,000	1.5	.58	4,350
Washington parent survey	2,000	1.5	.58	1,740
Washington process study interview	30	.5	.5	8
Massachusetts child assessments	700	1.5	.5	525
Massachusetts provider questionnaire	350	1	.16	56

Estimated Total Annual Burden Hours: 6,679.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information colleciton described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 15, 2005.

Robert Sargis,

Reports Clearance, Officer.

[FR Doc. 05–18771 Filed 9–20–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Refugee Resettlement

Grant to United States Conference of Catholic Bishops

AGENCY: Office of Refugee Resettlement, Administration for Children and Families (ACF), Department of Health and Human Services (DHHS).

ACTION: Award announcement.

CFDA#: The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.576. The title is the Refugee Family Enrichment Program.

Amount of Award: $194,000.

SUMMARY: Notice is hereby given that a noncompetitive single source program expansion supplement to an ongoing competitive award is being made to the United States Conference of Catholic Bishops (USCCB) in response to an unsolicited application. The application is not within the scope of any existing or expected to be issued program announcement for the Fiscal Year 2006. USCCB's application is expected to address issues critical to the development and implementation of marriage education programs for refugees by opening three new program sites.

In September of 2003, ORR awarded USCCB a grant of $1,000,000,000 to develop a Refugee Family Enrichment program which included technical assistance to subgrantees. Over the past two years, USCCB has established an effective program in sites that have successfully prepared thousands of refugee families for the challenges they will face during resettlement. Because other Refugee Marriage Enrichment grantees are primarily regional in scope, we believe USCCB is uniquely suited to effectively implement this supplemental award. USCCB has affiliates across the country and has no physical or

programmatic limitations regarding which ethnic groups they can serve. We believe that by allowing them to increase the number of sites, that it would be a cost-effective way of helping more refugees develop the skills that help their marriages succeed and give their children a better chance of success in the U.S. Without it, these sites might struggle to provide refugee clients with the programs they need in order to achieve self-sufficiency.

The proposed project period is 9/30/2005–9/29/2006.

Assistance to support grantees in developing better approaches to the delivery of services provided to refugees is authorized by section 412(c)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1522(c)(1)).

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families, Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., Washington, DC 20447, Loren Bussert—(202) 401–4732, *lbussert@acf.hhs.gov*.

Dated: September 15, 2005.

Nguyen Van Hanh,

Director, Office of Refugee Resettlement.

[FR Doc. 05–18847 Filed 9–20–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0143]

High Chemical Co. et al.; Withdrawal of Approval of 13 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 13 new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: Effective September 21, 2005.

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

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). In the **Federal Register** of January 28, 2005 (70 FR 4134), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 13 NDAs because the firms had failed to submit the required annual reports for these applications. On April 28, 2005, the agency withdrew that notice (70 FR 22054) and reissued the corrected NOOH (70 FR 22052). FDA received two responses to the NOOH:

1. The Kendall Co. (Kendall), 15 Hampshire St., Mansfield, MA 02048, notified the agency that they no longer market the following products: NDA 10–337, Fling Antiperspirant Foot Powder; NDA 10–823, BIKE Foot and Body Powder; and NDA 10–824, BIKE Anti-Fungal Aerosol Spray. Kendall informed FDA that their historical files show they sold their rights to these three products (including the licenses) many years ago; however, they did not notify the agency of the sale. Because Kendall sold the products many years ago, they have no record of the new application holder. Neither The Kendall Co. nor the new license holder requested a hearing.

2. Bayer HealthCare LLC, Biological Products Division, 800 Dwight Way, Berkeley, CA 94701–1966, notified the agency that NDA 10–541, BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder, is not a product produced at their Berkeley site, and that they would forward the NOOH to Bayer HealthCare LLC, Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516–4175. Bayer HealthCare LLC in West Haven, CT, informed the agency that NDA 10–541, BY-NA-MID, is not their product and that they have no regulatory files for this product. Bayer HealthCare LLC did not request a hearing.

No other firms responded to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the 13 applications listed in the table of this document.

Application No.	Drug	Applicant
NDA 0–763	Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))	High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122
NDA 2–959	Nicotinic Acid (Niacin) Tablets	The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102
NDA 4–236	Sherman (thiamine HCl) Elixir	Do.
NDA 4–368	Ascorbic Acid Tablets	Do.
NDA 5–159	D.S.D. (diethylstilbestrol dipropionate)	Do.
NDA 9–452	Multifuge (piperazine citrate) Syrup	Do.
NDA 10–055	Fire Gard Three-Alarm Burn Relief (Methylcellulose)	Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520
NDA 10–337	Fling Antiperspirant Foot Powder	Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA 02110
NDA 10–541	BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder	Miles Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701
NDA 10–823	BIKE Foot and Body Powder	Bauer & Black, A Division of The Kendall Co.
NDA 10–824	BIKE Anti-Fungal Aerosol Spray	Do.
NDA 11–233	TKO with Entrin Roll-On Liquid	Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504
NDA 19–432	Spectamine (Iofetamine Hydrochloride I–123) Injection	IMP Inc., 8050 El Rio, Houston, TX 77054

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner of Food and Drugs, finds that the holders of the applications