ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Recruitment screener	252	1	5/60	21
Exploratory Focus Groups	72	1	2	144
Message Testing Focus Groups	54	1	2	108
Total				273

Dated: June 3, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–14873 Filed 6–18–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Revision to Proposed Collection; Comment Request; The National Children's Study (NCS), Vanguard (Pilot) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 22, 2010, pages 14165–14168, and allowed 60 days for public comment. One comment was received. The comment questioned the value and utility of the proposed data collection, stating that this type of research is not needed. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Pilot Study for the National Children's Study, *Type of Information Collection Request:* Revision, *Affected entities:* Households and individuals. *Types of respondents:* People potentially affected by this action are pregnant women, women age 18–49 years of age, their husbands or partners, and their children who live in selected areas within National Children's Study sites. Health care professionals, community leaders, and child care personnel are also potentially affected. *Frequency of Response:* On occasion. See burden table for estimated number of annual responses for each respondent. *Need and use of information collection:* The purpose of the proposed methodological study is to evaluate the feasibility, acceptability, and cost of three separate recruitment strategies for enrollment of women into a prospective, national longitudinal study of child health and development. This Recruitment Substudy is a component of the Vanguard Phase of the National Children's Study (NCS). In combination, the studies in the Vanguard Phase will be used to inform the design of the Main Study of the National Children's Study.

This data collection will evaluate the feasibility, acceptability and cost of three separate recruitment strategies for enrollment of women into the NCS. Up to 30 additional sites will be added to the NCS Vanguard Cohort, as reflected in the burden table, in order to ensure an adequate cohort size. These additional sites will be chosen from among those already identified for the Main Study of the NCS. Across these additional sites, three alternate recruitment strategies will be assessed:

- An enhanced household enumeration strategy that builds on the lessons learned in the existing Vanguard Study by enhancing enumeration techniques and employing a more streamlined recruitment process;
- A provider based recruitment strategy that relies on health care providers for assistance in participant identification and recruitment; and
- A two-tiered recruitment strategy that relies on larger secondary sampling units to increase the number of geographically-eligible women in a given area, and allows for both higher-intensity and lower-intensity forms of data collection.

The feasibility (technical performance), acceptability (respondent tolerance and impact on study infrastructure), and cost (operations, time, and effort) of each of these three strategies will be evaluated using pre-determined measures. The findings will be assessed and used to inform the strategies, or combinations of strategies, that might be used in the Main Study of the NCS. Further details pertaining to the NCS background and planning can be found at: *http://www.nationalchildrensstudy.gov.*

Burden statement: The public burden for this study will vary depending on the eligibility and pregnancy status of potential participants at the time of household screening and the method of recruitment. The table below provides an annualized average burden per person for each stage of the Recruitment Substudy.

TABLE A.2—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1

[July 2010 to December 2010]

Recruitment strategy	Activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
Provider-based: 10 Study Locations			**Projected for Stage 1 (July 2010–December 2010)**			
	Screening Activities					
	Address Look-Up	Age-Eligible Women.	7,500	1	0.1	750

TABLE A.2—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1—Continued
[July 2010 to December 2010]

Recruitment strategy	Activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
	Pregnancy Screening	Age-Eligible Women.	1,500	1	0.42	630
	Preconception Activities					
	Pre-Pregnancy Interview	Age-Eligible Women.	123	1	0.75	92
	Pregnancy Probability Group Follow Up Script.	Age-Eligible Women.	123	6	0.1	74
	Pregnancy Activities					
	Women's Informed Consent Form.	Pregnant Women	1,500	1	0.67	1,005
	Pregnancy Visit 1 Interview	Pregnant Women	572	1	1	572
	Pregnancy Visit 2 Interview	Pregnant Women	572	1	0.75	429
	Birth-Related Activities					
	Birth Visit Interview	Mother/Baby	299	1	0.4	120
	Total—Stage 1		12,188			3,671
Enhanced Household: 10 Study Locations			**Projected for Stage 1 (July 2010–December 2010)**			
	Screening Activities					
	Household Enumeration Script.	HH reporters	120,000	1	0.33	39,600
	Pregnancy Screening	Age-Eligible Women.	51,198	1	0.42	21,503
	Neighbor Report	Neighbors	12,000	1	0.05	600
	Preconception Activities					
	Pre-Pregnancy Interview	Age-Eligible Women.	211	1	0.75	158
	Pregnancy Probability Group Follow Up Script.	Age-Eligible Women.	211	6	0.1	127
	Pregnancy Activities					
	Women's Informed Consent Form.	Pregnant Women	2,586	1	0.67	1,733
	Pregnancy Visit 1 Interview	Pregnant Women	986	1	1	986
	Pregnancy Visit 2 Interview	Pregnant Women	986	1	0.75	740
	Birth-Related Activities					
	Birth Visit Interview	Mother/Baby	516	1	0.4	206
	Total—Stage 1		188,695			65,653
Two Tier (Low): 10 Study Locations Across Both Tiers			**Projected for Stage 1 (July 2010–December 2010)**			
	Screening Activities					
	Low-intensity CATI Preg. Screener.	Age-Eligible Women.	48,000	1	0.35	16,800
	Low-Intensity Consent Script.	Age-Eligible Women.	28,800	1	0.33	9,504
	Preconception Activities					
	Low-intensity CATI Questionnaire.	Age-Eligible Women.	10,057	1	0.5	5,028
	Pregnancy Probability Group Follow Up Script.	Age-Eligible Women.	10,057	6	0.1	6,034
	Pregnancy Activities					
	Low-intensity CATI Questionnaire.	Pregnant Women	518	1	0.5	259
	Birth-Related Activities					
	Low-intensity CATI Questionnaire.	Mother/Baby	166	1	0.5	83
	Total—Stage 1		97,598			37,709
Two Tier (High): 10 Study Locations Across Both Tiers			**Projected for Stage 1 (July 2010–December 2010)**			
	Screening Activities					
	Pregnancy Screening	Age-Eligible Women.	15,840	1	0.42	6,653
	Preconception Activities					
	Pre-Pregnancy Interview	Age-Eligible Women.	761	1	0.75	571

TABLE A.2—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1—Continued
[July 2010 to December 2010]

Recruitment strategy	Activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
	Pregnancy Probability Group Follow Up Script.	Age-Eligible Women.	761	6	0.1	456
	Pregnancy Activities					
	Women's Informed Consent Form.	Pregnant Women ..	9,504	1	0.67	6,368
	Pregnancy Visit 1 Interview	Pregnant Women ..	3,552	1	1	3,552
	Pregnancy Visit 2 Interview	Pregnant Women ..	3,552	1	0.75	2,664
	Birth-Related Activities					
	Birth Visit Interview	Mother/Baby	1,857	1	0.4	743
	Total—Stage 1	.....	35,826	.....	.....	21,006
Grand Total, Recruitment Substudy		.....	334,308	.....	.....	128,039

The estimated annualized cost to respondents is $1,782,053 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, *Attention:* Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jamelle E. Banks, M.P.H., National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 443–7210, or e-mail your request, including your address to *banksj@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 15, 2010.

Jamelle E. Banks,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–14969 Filed 6–18–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0002]

Notice of Approval of a Supplemental New Animal Drug Application; Penicillin G Procaine Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Norbrook Laboratories, Ltd. The supplemental NADA provides for a revised formulation of penicillin G procaine injectable suspension that includes lecithin as a surfactant.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed a supplement to NADA 065–010 for use of NOROCILLIN (penicillin G procaine) Injectable Suspension by intramuscular injection in cattle, sheep, swine, and horses. The supplement provides for a revised formulation that includes lecithin as a surfactant. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and part 514 (21 CFR 514), in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of April 23, 2010.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.