to understand current provider knowledge, attitudes, and practices regarding maternal opioid use.

CDC, in collaboration with the American College of Obstetricians and Gynecologists (ACOG), plans to conduct a survey to address this gap in knowledge. Survey respondents will be ACOG Fellows and Junior Fellows who have a current medical license and are in medical practice focused on women's health. ACOG is separated into 11 districts, one of which represents OB/GYN members who are in the U.S. military. The remaining 10 ACOG districts correspond to geographic regions that encompass the entire United States and Canada. Survey invitations will be sent to a quasi-random sample of ACOG members in each district.

CDC and ACOG estimate that 1,500 individuals will be contacted in order to obtain a study target of 600 respondents. The initial invitation will be distributed by email with instructions on completing a web-based version of the questionnaire. Three to four months after the initial invitation, a paper version of the questionnaire will be distributed to individuals who have not completed the online version. The estimated number of respondents for the full web-based or paper questionnaire is 420 and the estimated burden per response is 15 minutes. Approximately 6 weeks after the second recruitment attempt, ACOG will distribute a short version of the questionnaire to any non-responders. The estimated number of responses for the short version of the questionnaire is 180 and the estimated burden per response is 5 minutes. An overall 40% response rate is expected.

The survey will collect information about provider attitudes and beliefs regarding maternal opioid use, their screening and referral practices for pregnant or postpartum patients, barriers to screening and treating pregnant and postpartum patients for opioid use, and resources that are needed to improve treatment and referral. No information will be collected about individual patients. Survey administration and data management will be conducted by ACOG, and participation is voluntary. De-identified response data will be shared with CDC for analysis. Findings will be used to create recommendations for educational programs and patient care. The total estimated annualized burden hours are 120. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
OB/GYNs caring for pregnant women.	Practice Patterns related to Opioid Use during Pregnancy and Lactation—Full survey.	420	1	15/60
	Practice Patterns related to Opioid Use during Pregnancy and Lactation—Short introduction and survey.	180	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–21273 Filed 9–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Ethnic Community Self-Help Program Data Indicators.

OMB No.: 0970–NEW.

Description: The ACF Office of Refugee Resettlement proposes to collect information from Ethnic Community-Based Organizations (ECBOs) awarded federal funds under HHS–2016–ACF–ORR–1129. The information, collected through a questionnaire, is expected to provide information on Program objectives semi-annually in order for program staff to gauge the Program's progress for reporting and evaluation purposes.

Respondents: ECBOs awarded under HHS–2016–ACF–ORR–1129.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ECSH Data Indicators	10	2	1	20

Estimated Total Annual Burden Hours: 20.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–21250 Filed 9–2–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2526]

Determination That AQUAMEPHYTON (Phytonadione) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 012223	AQUAMEPHYTON	Phytonadione	10 milligram (mg)/milliliter (mL); 1 mg/0.5 mL.	Injectable; Injection	Teligent Pharma Inc.
NDA 016087	VALIUM	Diazepam	5 mg/mL	Injectable; Injection	Roche.
NDA 017090	TOFRANIL–PM	Imipramine Pamoate	Equivalent to (EQ) 75 mg HCl; EQ 100 mg HCl; EQ 125 mg HCl; EQ 150 mg HCl.	Capsule; Oral	Mallinckrodt Pharmaceuticals.
NDA 017558	ROBINUL	Glycopyrrolate	0.2 mg/mL	Injectable; Injection	Eurohealth International Sarl.
NDA 017911	CLINORIL	Sulindac	200 mg	Tablet; Oral	Merck.
NDA 017962	PARLODEL	Bromocriptine Mesylate.	EQ 5 mg base	Capsule; Oral	US Pharmaceuticals Holdings I LLC.
NDA 018579	FUROSEMIDE	Furosemide	10 mg/mL	Injectable; Injection	Luitpold Pharmaceuticals, Inc.
NDA 018687	NORMODYNE	Labetalol Hydrochloride.	100 mg; 200 mg; 300 mg; 400 mg.	Tablet; Oral	Schering-Plough Corp.
NDA 018731	BUSPAR	Buspirone Hydrochloride.	5 mg	Tablet; Oral	Bristol-Myers Squibb.
NDA 018776	NORCURON	Vecuronium Bromide	10 mg/vial; 20 mg/vial	Injectable; for Injection.	Organon USA Inc.
NDA 019773	VENTOLIN	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation	GlaxoSmithKline.
NDA 019810	PRILOSEC	Omeprazole	10 mg; 20 mg; 40 mg	Capsule, Delayed-Release Pellets; Oral.	AstraZeneca Pharmaceuticals LP.
NDA 020059	ADENOSCAN	Adenosine	60 mg/20 mL (3 mg/mL); 90 mg/30 mL (3 mg/mL).	Solution; I.V. Infusion	Astellas Pharma US, Inc.
NDA 020799	FLOXIN OTIC	Ofloxacin	0.3%	Solution/Drops; Otic	Daiichi-Sankyo.
NDA 021045	PLAN B	Levonorgestrel	0.75 mg	Tablet; Oral	Teva Branded Pharm.
NDA 021214	RESCULA	Unoprostone Isopropyl.	0.15%	Solution/Drops; Ophthalmic.	Sucampo Pharmaceuticals, Inc.
NDA 050459	AMOXIL	Amoxicillin	250 mg; 500 mg	Capsule; Oral	GlaxoSmithKline.