

variability in success rates across ART programs and individuals.

Each ART program reports its annual ART cycle data to CDC in mid-December. The annual data reporting consists of information about all ART cycles that were initiated in the previous calendar year. For example, the December 2017 reports described ART cycles that were initiated between January 1, 2016, and December 31, 2016. Data elements and definitions currently in use reflect CDC's prior consultations with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine, and RESOLVE: The National Infertility Association (a national, nonprofit consumer

organization), as well as a variety of individuals with expertise and interest in this field.

The estimated number of respondents (ART programs or clinics) is 464, based on the number of clinics that provided information in 2015; the estimated average number of responses (ART cycles) per respondent is 350. Additionally, approximately 5–10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the

feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 75% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years. The estimated annualized Burden Hours are 114,631 which is a decrease of 1,794 from the current OMB-approved collection. There are no costs to respondents 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)
ART Clinics .....	NASS .....	464	350	42/60
	Data Validation .....	35	70	23/60
	Feedback Survey .....	348	1	2/60

**Jeffrey M. Zirger,**

*Acting 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.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day–18–0222]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER), to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on March 1, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30

days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions

regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

**Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB Control Number 0920–0222, Expiration 07/31/2018)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC)**

*Background and Brief Description*

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data to support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) is the focal point within NCHS for questionnaire and survey development, pre-testing, and evaluation activities for CDC surveys (such as the NCHS National Health

Interview Survey, OMB No. 0920–0214) and other federally sponsored surveys. NCHS is requesting 3 years of OMB Clearance for this generic submission.

The CCQDER and other NCHS programs conduct cognitive interviews, focus groups, in-depth or ethnographic interviews, usability tests, field tests/pilot interviews, and experimental research in laboratory and field settings, both for applied questionnaire development and evaluation as well as more basic research on measurement errors and survey response.

Various techniques to evaluate interviewer administered, self-administered, telephone, Computer Assisted Personal Interviewing (CAPI), Computer Assisted Self-Interviewing (CASI), Audio Computer-Assisted Self-Interviewing (ACASI), and web-based questionnaires are used.

The most common questionnaire evaluation method is the cognitive interview. These evaluations are conducted by the CCQDER and contractors, as needed. The interview structure consists of respondents first answering a draft survey question and then providing textual information to reveal the processes involved in answering the test question. Specifically, cognitive interview respondents are asked to describe how and why they answered the question as they did. Through the interviewing process, various types of question-response problems that would not normally be identified in a traditional survey interview, such as interpretive errors and recall accuracy, are uncovered. By conducting a comparative analysis of cognitive interviews, it is also possible to determine whether particular interpretive patterns occur within particular sub-groups of the population.

Interviews are generally conducted in small rounds totaling 40–100 interviews; ideally, the questionnaire is re-worked between rounds, and revisions are tested iteratively until interviews yield relatively few new insights.

Cognitive interviewing is inexpensive and provides useful data on questionnaire performance while minimizing respondent burden. Cognitive interviewing offers a detailed depiction of meanings and processes used by respondents to answer questions—processes that ultimately produce the survey data. As such, the method offers an insight that can transform understanding of question validity and response error. Documented findings from these studies represent tangible evidence of how the question performs. Such documentation also serves CDC data users, allowing them to be critical users in their approach and application of the data.

In addition to cognitive interviewing, a number of other qualitative and quantitative methods are used to investigate and research measurement error and the survey response process. These methods include conducting focus groups, usability tests, in-depth or ethnographic interviews, and the administration and analysis of questions in both representative and non-representative field tests. Focus groups are conducted by the CCQDER and contractors, as needed. They are group discussions whose primary purpose is to elicit the basic sociocultural understandings and terminology that form the basis of questionnaire design. Each group typically consists of one moderator and 4 to 10 participants, depending on the research question. In-depth or ethnographic interviews are one-on-one interviews designed to elicit

the understandings or terminology that are necessary for question design, as well as to gather detailed information that can contribute to the analysis of both qualitative and quantitative data. Usability tests are typically one-on-one interviews that are used to determine how a given survey or information collection tool functions in the field, and how the mode and layout of the instrument itself may contribute to survey response error and the survey response process.

In addition to these qualitative methods, NCHS also uses various tools to obtain quantitative data, which can be analyzed alone or analyzed alongside qualitative data to give a much fuller accounting of the survey response process. For instance, phone, internet, mail, and in-person follow-up interviews of previous NCHS survey respondents may be used to test the validity of survey questions and questionnaires and to obtain more detailed information that cannot be gathered on the original survey. Additionally, field or pilot tests may be conducted on both representative and non-representative samples, including those obtained from commercial survey and web panel vendors. Beyond looking at traditional measures of survey errors (such as item missing and non-response rates, and response latency), these pilot tests can be used to run experimental designs in order to capture how different questions function in a field setting.

Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. There are no costs to respondents other than their time. The total estimated annual burden hours are 7,783.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals or households .....	Eligibility Screening .....	4,000	1	5/60
Individuals or households .....	Questionnaire Development Studies .....	7,300	1	55/60
Individuals or households .....	Respondent Data Collection Sheet .....	7,300	1	5/60
Individuals or households .....	Focus groups .....	100	1	90/60

**Jeffery M. Zirger,**

*Acting 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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Advisory Committee to the Director, Centers for Disease Control and Prevention—Health Disparities Subcommittee (ACD, CDC—HDS). This meeting is open to the public, limited only by the 50 audio phone lines. The public is also welcome to listen to the meeting by teleconference. Please dial (866) 918-8397 and enter code 9346283. There are 50 lines available. The public comment period is from 3:15 p.m.–3:20 p.m.

**DATES:** The meeting will be held on October 9, 2018, 1:30 p.m. to 3:30 p.m., EDT.

**ADDRESSES:** Teleconference phone (866) 918-8397 and enter code 9346283.

**FOR FURTHER INFORMATION CONTACT:** Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road NE, M/S K-77, Atlanta, Georgia 30329. Telephone (404) 498-6482, Email: [ACDDirector@cdc.gov](mailto:ACDDirector@cdc.gov).

#### **SUPPLEMENTARY INFORMATION:**

*Purpose:* The Subcommittee will provide counsel to the CDC Director through the ACD on strategic and other health disparities and health equity issues and provide guidance on opportunities for CDC.

*Matters to be Considered:* The agenda will include discussions on new member orientation. This meeting will provide information to new members regarding their role & duties on this subcommittee. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated

the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Dia Taylor,**

*Acting Chief Operating Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-P-1283]

#### Determination That Metaxalone Tablets, 640 Milligrams, 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 metaxalone tablets, 640 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for metaxalone tablets, 640 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Glen Cheng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, 301-796-1494.

**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 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 known generally as the “Orange Book.” Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Metaxalone tablets, 640 mg, are the subject of NDA 22-503, held by Primus Pharmaceuticals, Inc., and initially approved on June 1, 2015. Metaxalone tablets, 640 mg, are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

In a letter dated September 30, 2015, the previous NDA holder CorePharma, LLC notified FDA that metaxalone tablets, 640 mg, were discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Sovereign Pharmaceuticals, LLC submitted a citizen petition dated March 26, 2018 (Docket No. FDA-2018-P-1283), under 21 CFR 10.30, requesting that the Agency determine whether metaxalone tablets, 640 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that metaxalone tablets, 640 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that metaxalone tablets, 640 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of metaxalone tablets, 640 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was