thirty (30) days, following a user's deletion of his or her account.

Part IV of the proposed order requires Facebook to establish and maintain a comprehensive privacy program that is reasonably designed to: (1) Address privacy risks related to the development and management of new and existing products and services, and (2) protect the privacy and confidentiality of covered information. The privacy program must be documented in writing and must contain controls and procedures appropriate to Facebook's size and complexity, the nature and scope of its activities, and the sensitivity of covered information. Specifically, the order requires Facebook to:

- Designate an employee or employees to coordinate and be responsible for the privacy program;
- Identify reasonably-foreseeable, material risks, both internal and external, that could result in the unauthorized collection, use, or disclosure of covered information and assess the sufficiency of any safeguards in place to control these risks;
- Design and implement reasonable controls and procedures to address the risks identified through the privacy risk assessment and regularly test or monitor the effectiveness of these controls and procedures;
- Develop and use reasonable steps to select and retain service providers capable of appropriately protecting the privacy of covered information they receive from respondent, and require service providers by contract to implement and maintain appropriate privacy protections; and
- Evaluate and adjust its privacy program in light of the results of the testing and monitoring, any material changes to its operations or business arrangements, or any other circumstances that it knows or has reason to know may have a material impact on the effectiveness of its privacy program.

Part V of the proposed order requires that Facebook obtain within 180 days, and every other year thereafter for twenty (20) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that it has in place a privacy program that provides protections that meet or exceed the protections required by Part IV of the proposed order; and its privacy controls are operating with sufficient effectiveness to provide reasonable assurance that the privacy of covered information is protected.

Parts VI through X of the proposed order are reporting and compliance provisions. Part VI requires that Facebook retain all ''widely disseminated statements'' that describe the extent to which respondent maintains and protects the privacy, security, and confidentiality of any covered information, along with all materials relied upon in making such statements, for a period of three (3) years. Part VI further requires Facebook to retain, for a period of six (6) months from the date received, all consumer complaints directed at Facebook, or forwarded to Facebook by a third party, that relate to the conduct prohibited by the proposed order, and any responses to such complaints. Part VI also requires Facebook to retain for a period of five (5) years from the date received, documents, prepared by or on behalf of Facebook, that contradict, qualify, or call into question its compliance with the proposed order. Part VI additionally requires Facebook to retain for a period of three (3) years, each materially different document relating to its attempt to obtain the affirmative express consent of users referred to in Part II, along with documents and information sufficient to show each user's consent and documents sufficient to demonstrate, on an aggregate basis, the number of users for whom each such privacy setting was in effect at any time Facebook has attempted to obtain such consent. Finally, Part VI requires that Facebook retain all materials relied upon to prepare the third-party assessments for a period of three (3) years after the date that each assessment is prepared.

Part VII requires dissemination of the order now and in the future to principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities relating to the subject matter of the order. Part VIII ensures notification to the FTC of changes in corporate status. Part IX mandates that Facebook submit an initial compliance report to the FTC and make available to the FTC subsequent reports. Part X is a provision ''sunsetting'' the order after twenty (20) years, with certain exceptions.

The purpose of the analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011–31158 Filed 12–2–11; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–12–11DU]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

The National Survey of Prison Health Care (NSPHC)—New—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 collect statistics on the extent and nature of illness and disability of the population of the United States. This one-year clearance request includes data collection from identified respondents at the Department of Corrections within each state in the United States and the Federal Bureau of Prisons.

Few national level data exist concerning the administration of health care services in correctional facilities in the United States. National-level data from the health care providers within prison systems are important for a myriad of purposes related to improving prison health and health care. To remedy this gap in knowledge regarding the capacity of prison facilities to deliver medical and mental health services, NCHS in partnership with the Bureau of Justice Statistics (BJS) plans to conduct the National Survey of Prison Health Care (NSPHC). This collection aims to: provide an overall picture of the global structure of healthcare services in prisons in the United States; close gaps in available information about availability, location and capacity of healthcare services provided to inmates; and identify extent

to which electronic medical records are utilized within the correctional healthcare system.

NSPHC will be a mail survey to a prison official in the Department of Corrections (DOC) within each of the 50 States and Federal Bureau of Prisons (BOP) and will seek facility-level information on the types of healthcare services delivered and the mechanisms used to deliver these services.

NSPHC will collect data on healthcare services including the extent to which services are contracted; staffing; locations (*i.e.,* on- or off-site) of healthcare services and specialty healthcare services; and the types of of medical, dental, mental health, and pharmaceutical services provided to inmates. NSPHC will collect data on intake physical and mental health assessments practices for inmates; credentials of staff performing screenings; vaccinations against major infectious diseases; and smoking allowances. Discharge planning data collected includes the availability of bridge medications, Medicaid re-enrollment processes, and the number of inmates with mental illness linked to housing prior to release. NSPHC will also collect data on how DOCs maintain health records including the format (paper and/or electronic) of specific types of health records.

Potential users of the data collected through NSPHC are policy makers, correctional healthcare researchers, mental health researchers, and corrections administrators. There is no cost to respondents other than their time to participate. The total estimated annual burden is 204 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Prison official in DOC or BOP (Medical/Health Researcher)	NSPHC Questionnaire	51	1	4

Dated: November 28, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31108 Filed 12–2–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0826]

Determination That DEMULEN 1/50–28 (Ethinyl Estradiol; Ethynodiol Diacetate) Tablet and Four 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) has determined that the five 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: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 reasons of safety or effectiveness, 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	Applicant
NDA 016936	DEMULEN 1/50–28 (ethinyl estradiol; ethynodiol diacetate) Tablet, 0.05 mg; 1 mg.	GD Searle, LLC, 4901 Searle Pkwy., Skokie, IL 60077.
NDA 018160	DEMULEN 1/35–28 (ethinyl estradiol; ethynodiol diacetate) Tablet, 0.035 mg; 1 mg.	Do.