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That DEMULEN 1/50–28 (Ethinyl Estradiol; Ethynodiol Diacetate) Tablet and Four Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the five drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.

Application No.	Drug	Applicant
NDA 018168	DEMULEN 1/35–21 (ethinyl estradiol; ethynodiol diacetate) Tablet, 0.035 mg; 1 mg.	Do.
NDA 019190	TRIPHASIL–28 (ethinyl estradiol; levonorgestrel) Tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 019192	TRIPHASIL–21 (ethinyl estradiol; levonorgestrel) Tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31146 Filed 12–2–11; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0176]

SEDASYS Computer-Assisted Personalized Sedation System; Ethicon Endo-Surgery, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; Notice of Cancellation of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Medical Devices Dispute Resolution Panel scheduled for December 14, 2011, is cancelled. This meeting was announced in the **Federal Register** of November 21, 2011 (76 FR 71980).

FOR FURTHER INFORMATION CONTACT: Nancy Braier, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 5454, Silver Spring, MD 20993–0002, (301) 796–5676, FAX: (301) 847–8510, email: *nancy.braier@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The meeting of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee scheduled for December 14, 2011, is cancelled. On December 14, 2011, this advisory committee was slated to discuss the Center for Devices and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for the SEDASYS computer-assisted personalized sedation system (SEDASYS) submitted by Ethicon Endo-Surgery Inc. (EES), the sponsor for SEDASYS. This meeting has been cancelled because EES has withdrawn its petition for review of this denial.

On February 26, 2010, CDRH issued a letter to EES indicating that PMA P080009 for SEDASYS was not approvable under § 814.44(f) (21 CFR 814.44(f)) because CDRH concluded that the data and information offered in support of the PMA did not provide a reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(2)(A)).

On March 25, 2010, EES requested review of the not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (see 21 CFR 814.44(f)(2)), EES's petition stated that, in accordance with § 814.44(f), EES considered the not approvable letter to be a denial of approval of PMA P080009 under § 814.45 (21 CFR 814.45). In accordance with section 515(d)(4) of the FD&C Act, EES requested review of this denial under section 515(g)(2) of the FD&C Act. Subsequently, on October 26, 2010, CDRH issued an order denying approval of the SEDASYS PMA (Denial Order), as required by § 814.45(e)(3). On November 5, 2010, in accordance with section 515(g)(2) of the FD&C Act, FDA granted EES's petition for review of the Denial Order.

FDA's Office of the Commissioner (OC) referred PMA P080009 and the basis for CDRH's Denial Order to the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee, an advisory committee of experts established, in part, to receive referrals of petitions for advisory committee review under section 515(g)(2)(B) of the FD&C Act. (See 76 FR 15321, March 21, 2011.) In the **Federal Register** of November 21, 2011, FDA announced that this advisory committee was scheduled to meet to discuss the clinical and scientific issues raised by CDRH's Denial Order on December 14, 2011.

By letter dated November 28, 2011, EES notified OC that EES ''withdraws its request for administrative review'' of that order ''through an independent advisory committee under Section 515(g)(2) of the Federal Food, Drug, and Cosmetic Act.'' Because EES has withdrawn its petition for review of CDRH's denial of approval of the SEDASYS PMA, OC regards the matter it initiated closed and is, accordingly, canceling the previously mentioned meeting of the Medical Devices Dispute Resolution Panel scheduled for December 14, 2011.

Dated: November 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31105 Filed 12–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.