Users of NHAMCS data include, but are not limited to, congressional offices, Federal agencies, state and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, and health planners. NCHS is seeking OMB approval to extend this survey for an additional three years. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Hospital induction	490	1	55/60	449
ED induction	400	1	1	400
OPD induction	250	4	1	1,000
ED Patient record form	400	100	5/60	3,333
OPD Patient record form	250	200	5/60	4,167
CCSS	250	1	15/60	63
Total				9,412

Dated: January 5, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–0234]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–4766 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Ambulatory Medical Care Survey (NAMCS) 2007–2008 (OMB No. 0920–0234)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

The NAMCS was conducted annually from 1973 to 1981, again in 1985, and resumed as an annual survey in 1989. The purpose of NAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States. Ambulatory services are rendered in a wide variety of settings, including physicians' offices and hospital outpatient and emergency departments. The NAMCS target population consists of all office visits made by ambulatory patients to non-Federal office-based physicians (excluding those in the specialties of anesthesiology, radiology, and pathology) who are engaged in direct patient care. For the first time in 2006, physicians and mid-level providers (*i.e.*, nurse practitioners, physician assistants, and nurse midwives) practicing in community health centers (CHCs) were added to the NAMCS sample, and these data will continue to be collected in 2007–2008. To complement NAMCS data, NCHS initiated the National Hospital Ambulatory Medical Care Survey (NHAMCS, OMB No. 0920–0278) to provide data concerning patient visits to hospital outpatient and emergency departments.

The NAMCS provides a range of baseline data on the characteristics of the users and providers of ambulatory medical care. Data collected include the patients' demographic characteristics, reason(s) for visit, physicians' diagnosis(es), diagnostic services, medications, and visit disposition. In addition, a Cervical Cancer Screening Supplement (CCSS) will continue to be a key focus in 2007–2008. The CCSS collects information on cervical cancer screening practices performed by selected physician specialties. It will allow the CDC/National Center for Chronic Disease Prevention and Health Promotion to evaluate cervical cancer screening methods and the use of human papillomavirus tests.

Users of NAMCS data include, but are not limited to, congressional offices, Federal agencies, state and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, and health planners. NCHS is seeking OMB approval to extend this survey for an additional three years. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs)	Total burden hours
Office-based physicians:				
Induction Interview	3,350	1	28/60	1,563
Patient Record Form	2,513	30	4/60	5,026
CCSS	712	1	15/60	178
Community Health Center:				
Induction Interview—Directors	104	1	20/60	35
Induction Interview—Providers	312	1	35/60	182
Patient Record Form	312	30	5/60	780
CCSS	312	1	15/60	78
Total				7,842

Dated: January 5, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004P–0406 and 2004P–0407]

Determination That Celestone Soluspan (Betamethasone Sodium Phosphate and Betamethasone Acetate) Injection and Celestone (Betamethasone Sodium Phosphate) Injection 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) is announcing its determination that two drug products—Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection and Celestone (betamethasone sodium phosphate) injection—were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for betamethasone sodium phosphate and betamethasone acetate injection and betamethasone sodium phosphate injection if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for betamethasone sodium phosphate and betamethasone acetate injection, future applicants are advised that Celestone Soluspan injection may not be commercially available because, under a consent decree between FDA and the manufacturer, it is being made available in certain instances of medical necessity only. The reasons for its unavailability are not safety or effectiveness considerations associated with the drug product in general, but specific to the manufacturer. An ANDA applicant who is unable to obtain Celestone Soluspan injection for bioequivalence testing must contact the Office of Generic Drugs for a determination of what is necessary to show bioavailability and same therapeutic effect. If the reference listed drug (RLD) product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 sponsors 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 under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 (the 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, drugs are withdrawn 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). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On September 7, 2004, Hikma Farmaceutica (Portugal) LDA submitted two citizen petitions (Docket Nos. 2004P–0406/CP1 and 2004P–0407/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection equivalent to 6 milligrams (mg) base/milliliter (mL) (NDA 14–602) and Celestone (betamethasone sodium phosphate) injection equivalent to 3 mg base/mL (NDA 17–561), both manufactured by Schering-Plough Corp. (Schering), were withdrawn from sale for reasons of safety or effectiveness. Celestone Soluspan injection and Celestone injection are corticosteroids used for their anti-inflammatory effects in disorders of many organ systems. Schering ceased manufacture of Celestone injection in March 2004, and it was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.