Poulsbo, Washington, and thereby indirectly acquire North Sound Bank, Poulsbo, Washington.

Board of Governors of the Federal Reserve System, April 14, 2000.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00–9885 Filed 4–19–00; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60 Day–00–33]

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, the Centers for Disease Control and Prevention (CDC) is providing an opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC/ATSDR Reports Clearance Officer at (404) 639–7090.

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 for other forms of information technology. Send comments to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

1. Proposed Projects

National Survey of Laboratory Practices for Selected Coagulation Tests in Hospital Laboratories—New—As part of the continuing effort to support public health objectives of treatment, disease prevention and surveillance programs, the Public Health Practice Program Office (PHPPO), Division of Laboratory Systems seeks to collect information on coagulation testing practices among U.S. hospital laboratories. The purpose of this project is to define the state of testing practices in a random sample of up to 800 U.S. hospital laboratories for selected coagulation analytes by conducting a questionnaire survey of these laboratories. The objectives of this survey are to collect data to assess the variability of selected analytical and non-analytical variables, such as normal ranges, used for selected coagulation tests. There has not been a systematic and nationally based survey of coagulation testing practices among U.S. hospital laboratories. Such a surveillance is needed due to the impact that coagulation testing practices can have on the diagnosis and management of coagulation disorders.

There is ample evidence of variability in coagulation testing practices based on published literature corresponding to experiences of individual institutions that deal with analytical (e.g., impact of instrument and kit reagents on laboratory results) as well as pre-analytical (such as specimen treatment) and post-analytical (such as results presentation) issues. However, there has not been a systematic survey of national hospital laboratories that has documented the nature and extent of such variability for selected coagulation tests. Preliminary observations document substantial inter-institutional variability in coagulation testing practices, with likely effect on patient outcome.

This study will explore current practices for one or more selected coagulation tests to document the extent and nature of variability in the testing processes. It is anticipated that information from this study will be used for several purposes. First, results from this project may be used in a future study in order to surmise the potential impact of various testing practices on patient outcomes. A second anticipated use of this study's results is to implement targeted laboratory improvement efforts. Finally, this study may form the basis for a future study to assess the extent and nature of problems in diagnosis and treatment of patients caused by inaccurate laboratory results. Because hypo- and hypercoagulability disorders are prevalent in the U.S. and they are defined to a great extent by laboratory tests, a well designed laboratory practice survey is expected to be of great public health significance for the nation.

We plan to sample up to 800 laboratories that perform selected coagulation tests. The time required to complete a survey will be approximately 0.5 hours. We anticipate that, of the respondents, approximately 80 will be Coagulation Laboratory Directors (physicians) and approximately 720 will be Coagulation Laboratory Supervisors. The total burden hours to complete the survey is estimated to be 400. Based on hourly wage estimates, the cost to respondents could be approximately $9,000. Because we expect the Laboratory Directors and Supervisors to complete the survey during their usual working hours. We anticipate that there will be no actual cost to the respondents.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Laboratory Director	80	1	30/60	40
Laboratory Supervisor	720	1	30/60	360
Totals	800	.....	.....	400

Dated: April 13, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–9886 Filed 4–19–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79N–0113; DESI 2847]

Parenteral Multivitamin Products; Drugs for Human Use; Drug Efficacy Study Implementation; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the conditions for marketing an effective adult parenteral multivitamin drug product that published in the **Federal Register** of September 17, 1984 (49 FR 36446). The agency is notifying manufacturers of modifications in the adult formulation and certain portions of the labeling for the products.

DATES: Supplements to approved new drug applications (NDA's) and abbreviated new drug applications (ANDA's) are due on or before June 19, 2000.

ADDRESSES: Communication in response to this notice should be identified with the reference number DESI 2847 and directed to the attention of the appropriate office named below.

Supplements to full NDA's (identify with NDA number): Division of Metabolic and Endocrine Drug Products (HFD–510), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Original ANDA's: Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Requests for opinion of the applicability of this notice to a specific product: Division of Prescription Drug Compliance and Surveillance (HFD–330), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

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

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 17, 1984 (49 FR 36446), FDA announced the conditions for marketing an effective parenteral multivitamin preparation. The effective 12-vitamin formulation set forth in the notice was based on the clinical evaluation of a guideline formulation recommended in 1975 by the American Medical Association (AMA). The notice also stated that, because parenteral multivitamin products are used and evaluated in patients with a variety of disease conditions, future adjustments to the formulation may be necessary.

On August 21, 1985, FDA's Division of Metabolic and Endocrine Drug Products and the AMA's Division of Personal and Public Health Policy sponsored a public workshop on ''Multivitamin Preparations for Parenteral Use.'' At the workshop, additional data from clinical testing of the 1975 AMA formulation and a variety of other data were presented and discussed in light of available information on parenteral vitamin therapy. After examining the data, the AMA–FDA workshop committee recommended that the dosage of vitamins B_1, B_6, C, and folic acid be increased and that vitamin K be added to the formulation. Based on a review of the committee's recommendations, the Director of the Center for Drug Evaluation and Research has concluded that the 1975 AMA formulation for parenteral multivitamins should be modified to reflect the advice of the committee.

Accordingly, this notice amends portions of the section *Conditions for Approval and Marketing* in the September 17, 1984, notice as follows (in accordance with current labeling practice, amounts previously listed in international units (IU) have been converted to weights):

Paragraph 1(a)(i) is revised as follows:

1. *Adult formulation (intended for ages 11 and older*)

Ingredient	Amount per Unit Dose
Fat Soluble Vitamins	
A (retinol)	1 milligram (mg)
D (ergocalciferol or cholecalciferol)	5 micrograms (μg)
E (alpha-tocopherol)	10 mg
K (phylloquinone)	150 μg
Water-Soluble Vitamins	
C (ascorbic acid)	200 mg
Folic acid	600 μg
Niacin	40 mg
B_2 (riboflavin)	3.6 mg
B_1 (thiamine)	6.0 mg
B_6 (pyridoxine)	6.0 mg
B_{12} (cyanocobalamin)	5 μg
Pantothenic acid	15.0 mg
Biotin	60 μg

2. *Labeling conditions.*

(a) The label must bear the statement ''Rx only.''

(b) *Indication.* Paragraph 2(b)(i)(a) is revised as follows (This language may be editorially adapted to a specific product's labeling, as appropriate.):

Adult. This formulation is indicated as a daily multivitamin maintenance dosage for adults and for children age 11 and above receiving parenteral