A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Arkansas National Bancshares, Inc., Bentonville, Arkansas; to engage *de novo*, with Sable Technology, Inc., in data processing activities. Sable will manage the technical aspects of development, Notificant will make substantial contributions to the design and functionality of software for home banking. In addition, Notificant will purchase the hardware and data lines necessary to make the software operational. Notificant also proposes to remarket this software through a proposed unchartered, unnamed company, pursuant to § 225.25(b)(7) of the Board's Regulation Y. Notificant and Sable will each own 50 percent of the voting shares of this proposed company.

Board of Governors of the Federal Reserve System, September 25, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96–25071 Filed 9-30-96; 8:45 am]

BILLING CODE 6210-01-F

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, October 7, 1996.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: September 27, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–25274 Filed 9–27–96; 3:44 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Application for Waiver of the two-year Foreign Residence Requirement of the Exchange Visitor Program–0990–0001—Extension—The application is used by institutions (colleges, hospitals, etc.) to request a favorable recommendation to the USIA for waiver of the two-year Foreign Residence Requirement of the Exchange Visitor Program on behalf of foreign visitors working in areas of interest to HHS. Respondents: Individuals, State or local governments, Businesses or other for-profit, non-profit institutions; Total Number of Respondents: 200; Frequency of Response: one time; Average Burden per Response: 6 hours; Estimated Annual Burden: 1200 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington DC 20201. Written comments should be received within 30 days of this notice.

Dated: September 23, 1996.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 96–25083 Filed 9–30–96; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 96N–0192]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a new harmonized application form, Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, Form FDA 356h. This form will apply to a wide range of products for human use that are regulated by both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), including drugs, biologics, and antibiotics. The form will replace a number of different application forms that are now used for these products.

DATES: Submit written comments on the collection of information by December 2, 1996.

ADDRESSES:

CDER Information: Submit written requests for single copies of the new harmonized application form, Form FDA 356h, to the Drug Information Branch (HFD–210), Division of Communications Management, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1012. Send one self-addressed adhesive label to assist that office in processing your requests. The form may also be obtained by calling the CDER FAX–ON–DEMAND System at 1–800–342–2722 or 1–301–827–0577.

CBER Information: Submit written requests for single copies of the new harmonized application form, Form FDA 356h, to the Division of Congressional and Public Affairs (HFM–44), Center for Biologics and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in

processing your requests. The form may also be obtained by FAX by calling the CBER Voice Information System at 1–800–835–4709.

Submit written comments on the new harmonized application form, Form FDA 356h, and its proposed use in the collection of information, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the new harmonized application form, Form FDA 356h, and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Use of Form FDA 356h

FDA is the Federal agency charged with responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, biologic, or an antibiotic drug for human use must file applications for FDA approval of the product prior to introducing it into interstate commerce. Statutory authority for the collection of this information is provided by sections 505(a), (b), and (j) and 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j) and 357) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). All manufacturers of new drugs and antibiotics for human use regulated under the act must submit an application for review and approval to CDER or CBER prior to marketing a drug or antibiotic in interstate commerce (21 CFR 314.50). All manufacturers of generic drugs, including generic antibiotic drugs for human use, regulated under the act must submit an abbreviated new drug application (ANDA) or an abbreviated antibiotic drug application (AADA) for review and approval to CDER prior to marketing a generic drug in interstate commerce (21 CFR 314.94). Most manufacturers of biological products regulated under the PHS Act must submit an establishment license application and a product license application for review and approval to CBER prior to marketing a biological product in interstate commerce (21 CFR 601.2). Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Manufacturers of a drug, biologic, or an antibiotic drug for human use are required to file supplemental applications for all important changes to applications previously approved prior to implementing such changes (21 CFR 314.70, 314.71, 314.97, and 601.12).

Form FDA 356h has been revised for CDER–regulated products to include identification of different types of supplemental applications. It has also been modified to include a section for establishment information pertaining to CBER-regulated products and the CBER licensing process.

The information provided by manufacturers with the revised application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs, biologics, and antibiotics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filing a drug application and has been previously used only by manufacturers of products regulated under the act. The revised form has been harmonized for use by manufacturers of products regulated under the act or under the PHS Act and will be used by industry regulated by both CDER and CBER. The harmonized application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form will also provide key information to the agency for efficient handling and distribution to the appropriate staff for review. The revised form will replace a number of different application forms that are now used for these products and is intended to help harmonize the application process.

FDA estimates the burden of this collection of information as follows:

There are no capital costs or operating and maintenance costs associated with this collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Type of Response[1]	No. of Respondents[2]	Annual Frequency per Response[3]	Total Annual Responses[4]	Hours per Response	Total Hours
NDA[5]	162	22.9	3,715	40	148,600
ANDA[6] and AADA[7]	350	18.6	6,517	40	260,680
ELA[8] and PLA[9]	391	4.9	1,905	40	76,200
Total Burden Hours					485,480

[1] Includes original applications and their amendments and supplemental applications
[2] Number of sponsors submitting applications during fiscal year (FY) 95
[3] Average number of applications submitted per sponsor

[4] Total applications submitted during FY 95
[5] New Drug Application (includes applications for new antibiotic drugs)
[6] Abbreviated New Drug Application
[7] Abbreviated Antibiotic Drug Application
[8] Establishment License Application
[9] Product License Application

In FY 95, CDER received a total of 10,232 submissions and CBER received 1,905 submissions that would require use of this application form. FDA estimates that 40 hours would be required for an industry regulatory affairs specialist to fill out the harmonized form, collate the documentation, and submit the application to CDER or CBER.

Dated: September 25, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–25076 Filed 9–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0236]

International Conference on Harmonisation; Draft Guideline on Data Elements for Transmission of Individual Case Safety Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Data Elements for Transmission of Individual Case Safety Reports.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to standardize the data elements for the electronic transmission of individual case safety reports for both preapproval and postapproval reporting periods.

DATES: Written comments by December 30, 1996.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1012, or written requests for single copies of the ICH documents can be submitted to the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or FAX by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709.

Persons with access to the INTERNET may obtain the document in several ways.

Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators (URL's):

http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requesters should connect to the FDA FTP Server, FTP.FDA.GOV (192.73.61.21). The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password.

The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both.

The document can be obtained by ''bounce-back e-mail''. A message should be sent to:

ICH__DATA@al.cber.fda.gov

Finally, an electronic version of this draft guideline is available via the U.S. Government Printing Office's ''GPO Access.'' Internet users can access the database through the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Richard M. Kapit, Center for Biologics Evaluation and Research (HFM–225), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3974.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

At a meeting held on April 30, 1996, the ICH Steering Committee agreed that a draft guideline entitled ''Data Elements for Transmission of Individual Case Safety Reports'' should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group. Ultimately, FDA intends to adopt the ICH Steering Committee's guideline.