GENERAL SERVICES ADMINISTRATION

Public Buildings Service

Virginia Avenue Border Crossing/San Ysidro Port of Entry, San Diego, California; Notice of Intent; Environmental Impact Statement

AGENCY: Public Buildings Service, GSA.

ACTION: Pursuant to the Council on Environmental Quality Regulations (40 CFR 1500–1508) implementing procedural provisions of the National Environmental Policy Act (NEPA), the United States General Services Administration (GSA) hereby gives notice that said agency intends to prepare an EIS on the Virginia Avenue Border Crossing/San Ysidro Port of Entry in San Diego, California. The proposed project would include construction of a small facility, four to six inspection lanes and inspection booths. The site compliments the Government of Mexico's planned new facility located at El Chaparral adjacent to Virginia Avenue to the south.

Alternatives: In addition to the proposed action, the EIS will examine two alternatives; realignment of Inter-State Highway 5 and no action or continued use of the existing San Ysidro Port Entry. Also, reasonable alternatives that may or may not be within the authority of GSA will be examined. If there are potentially a large number of alternatives, only a reasonable number of examples covering the full spectrum of alternatives shall be analyzed.

Public Involvement: There will be several public meetings including, Scoping, Critical Issue(s), Draft Review and Final EIS. There will also be public review and comment periods of the Draft EIS. Further information may be obtained from: Ms. Sheryll White, U.S. General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, 3rd Floor East, San Francisco, CA 94102–2799, Telephone: (415) 522–3488.

Dated: September 23, 1999.

Aki K. Nakao,

Deputy Regional Administrator, (9AD).

Notice of Intent To Prepare an EIS

The General Services Administration intends to prepare an Environmental Impact Statement (EIS) on the following project: Virginia Avenue Border Crossing/San Ysidro Port of Entry San Diego, California

The General Services Administration of the United States Government is proposing to expand the United States Border Crossing at Virginia Avenue in San Diego, California in order to provide southbound vehicular inspection and to convert the existing southbound lanes at the United States San Ysidro Port of Entry at San Diego, California to northbound.

Alternatives to the proposed action include:

A. Proposed Action: Construction of a small facility, four to six inspection lanes (initially) and inspection booths. The site complements the Government of Mexico's planned new facility at El Chaparral adjacent to Virginia Avenue to the south.

B. Realignment of Inter-State Highway 5 to increase northbound inspection lanes at the San Ysidro Port of Entry. This action could affect an historical residential area in Tijuana as well as traffic access to newly aligned lanes. The site is located to the east of the Government Mexico's planned new facility El Chaparral.

C. No action-space for functions now located at the San Ysidro Port of Entry will continue.

D. Reasonable alternatives which may or may not be within the authority of GSA. If there are potentially a large number of alternatives, only a reasonable number of examples covering the full spectrum of alternatives shall be analyzed.

Public scoping will include:

Scoping Meeting
Critical Issue(s) Meeting(s)
Public Review and Comment to Draft EIS
Draft EIS Review Meeting
Final EIS Meeting

FOR FURTHER INFORMATION CONTACT: Sheryll White, General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, 3rd Floor East, San Francisco, California 94102, (415) 522–3488, Fax: (415) 522–3215.
Email:sheryll.white@gsa.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4166]

Agency Information Collection Activities: Proposed Collection; Comment Request; Electronic Records; Electronic Signature

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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to FDA's electronic records and electronic signatures.

DATES: Submit written comments on the collection of information by November 30, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

Electronic Records; Electronic Signatures—Part 11 (21 CFR Part 11) (OMB Control Number 0910–0303)–Extension

The Food and Drug Administration (FDA) regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically, provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, state or local governments, Federal agencies, and nonprofit institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Record-keepers	Annual Fre-quency of Rec-ordkeeping	Total Annual Records	Hours per Rec-ordkeeper	Total Hours
11.10	2,250	1	2,250	20	45,000
11.30	2,250	1	2,250	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 24, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1651]

Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA.'' This draft guidance is intended to provide recommendations to holders of new animal drug applications (NADA's) and abbreviated new animal drug applications (ANADA's) on how they should report changes to such applications in accordance with proposed amended regulations that are found elsewhere in this issue of the **Federal Register**.

DATES: Written comments should be submitted by December 15, 1999.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Office of New Animal Drug Evaluation (HFV–140), Center for Veterinary Medicine, Food