docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 these topics: (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.

Generic FDA Rapid Response Surveys (OMB Control Number 0910–0500)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA, and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system. FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to obtain quickly vital information about medical product risks and interventions to reduce risks so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30 (maximum)	6,000	0.5	3,000

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

FDA projects 30 emergency risk-related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only 1 time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–258 Filed 1–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4001]

Memorandum of Understanding Between the Food and Drug Administration and Customs and Border Protection, Department of Homeland Security

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and Customs and Border Protection (CBP), Department of Homeland Security to allow FDA to commission CBP officers.

DATES: The agreement became effective December 3, 2003.

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regional Operations (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6230.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-04-4001

MEMORANDUM OF AGREEMENT BETWEEN CUSTOMS AND BORDER PROTECTION AND THE FOOD AND DRUG ADMINISTRATION

1. **Parties.** The parties to this Memorandum of Understanding (MOU) are Customs and Border Protection (CBP), Department of Homeland Security, and the Food and Drug Administration (FDA), Department of Health and Human Services.

2. **Authority.** The authorities for entering into this MOU are the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 372 and 381(m), 19 C.F.R § 12.1, 19 C.F.R. § 147.23, and 44 U.S.C. § 3510.

3. **Purpose.** The purpose of this MOU is to allow FDA to commission CBP officers. These commissioned officers will assist FDA with examinations and investigations pursuant to, or based on information obtained under, the prior notice requirements found in 21 U.S.C. § 381(m) and its implementing regulations, at ports and other facilities and locations subject to CBP jurisdiction.

4. **Responsibilities.**

A. The Food and Drug Administration agrees:

1. To commission all CBP officers deemed necessary by the Commissioners of CBP and FDA to conduct examinations and investigations in accordance with the prior notice requirements in 21 U.S.C. § 381(m) and its implementing regulations.

2. To provide appropriate training for the commissioned officers and employees that would allow them to conduct FDA examinations and investigations subject to this MOU.

3. To provide 24 hour operational and technical assistance to CBP for the stated purpose of this MOU.

4. To reimburse CBP for costs for training and costs incurred while performing FDA functions for which the CBP officers have been commissioned. Such reimbursement shall be pursuant to the terms of an interagency agreement to be negotiated between FDA and CBP.

5. To not disclose information received from CBP unless CBP approves, in advance, its disclosure in writing, including information contained in CBP databases.

6. To share information with CBP to fulfill the stated purpose of this MOU, such as information relating to bioterrorism threats, except as restricted by law.

7. To jointly develop and implement additional agreements and plans to help fulfill the stated purpose of this MOU.

B. Customs and Border Protection agrees:

1. To assist FDA in the execution of the prior notice requirements in 21 U.S.C. § 381(m) and its implementing regulations.

2. To collect samples upon FDA's request, and to forward those samples to FDA for analysis.

3. To collect and analyze samples upon FDA's request and to forward the results of the CBP analyses to FDA.

4. To share information with FDA to fulfill the stated purpose of this MOU.

5. To not disclose information received from FDA unless FDA approves, in advance, its disclosure in writing, including information contained in FDA databases.

6. To jointly develop and implement additional agreements and plans to help fulfill the stated purpose of this MOU.

5. **Date Effective.** The terms of this MOU will become effective upon signature of the parties. They will remain in effect until either modified or terminated as described in this MOU.

6. **Modification.** This MOU may be modified upon the mutual written consent of the Commissioner of Customs and Border Protection and the Commissioner of the Food and Drug Administration.

7. **Confidentiality.** CBP and FDA agree that any sharing of non-public information pursuant to this agreement will occur according to all applicable laws and regulations. Each agency understands that disclosure by the recipient of nonpublic information could be a violation of federal law.

8. **Termination.** Either party may revoke this MOU upon 30 days written notice.

9. **Severability Clause.** Nothing in this MOU is intended to conflict with the current laws, regulations, or directives of CBP or FDA. If a term of this MOU is inconsistent with such authority, then that term shall be invalid, but the remaining terms and conditions of this MOU shall remain in full force and effect.

10. **Emergency Situations.** In the event that a national or regional disaster disrupts communications between FDA and CBP, an emergency contingency plan shall become operational. The procedures of that system are to be agreed upon in an annex to this MOU.

11. **No Private Right of Action Created.** This intra-governmental MOU is not intended to create or confer any rights, privileges, or benefits for any private person or party.

12. **Relationship to Other Authorities.** Nothing in this MOU is intended to restrict CBP or FDA from taking any action that the agencies would be otherwise authorized to take under law.

13. **Contact Information for Liaison Offices.** The following offices will act as liaisons between FDA and CBP for the purpose of coordinating the implementation of this MOU:

A. Contact for FDA:
Director, Office of Regional Operations
Office of Regulatory Affairs
Food and Drug Administration
Rockville, MD 20857
(301) 443-6230

B. Contact for CBP:

Director, Special Enforcement
Office of Field Operations
Trade Compliance and Administration
Customs and Border Protection
Department of Homeland Security
(202) 927-0300

The undersigned approve the terms and conditions of this MOU and represent that they have the requisite authority to enter into it.

Douglas M. Browning, Deputy Commissioner
United States Customs and Border Protection
Department of Homeland Security

Date: 12/3/03

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
Department of Health and Human Services

Date: Dec 3 2003

[FR Doc. 04–260 Filed 1–6–04; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0571]

Draft Guidance for Industry on Drug Substance; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Drug Substance: Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug substances that should be submitted to support original new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), and abbreviated new animal drug applications (ANADAs). The draft guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit written or electronic comments on the draft guidance by July 5, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Steve Miller, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2392, or

Chris Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–435–5681, or

Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Substance: Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on the drug substance information to be submitted in NDAs, ANDAs, NADAs, and ANADAs to ensure continued drug substance and drug product quality (i.e., the identity, strength, quality, purity, and potency). Recommendations are provided on the information that should be included for: (1) Nomenclature, structure, and general drug substance properties, (2) manufacture, (3) characterization, (4) control of drug substance, (5) reference standards or materials, (6) container closure system, and (7) stability. The draft guidance is structured to facilitate the preparation of applications submitted in CTD format. The draft guidance, when finalized, will replace the guidance entitled ''Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substance'' (February 1987).

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control numbers 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the