to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Commonwealth of Virginia to have been affected adversely by this declared major disaster:

The independent cities of Chesapeake, Norfolk, Portsmouth, Suffolk, and Virginia Beach for Individual Assistance.

All counties within the Commonwealth of Virginia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 98–25186 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting; Announcing an Open Meeting of the Board

TIME AND DATE: 10:00 A.M., Wednesday, September 23, 1998.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:

- Mortgage Partnership Finance Program: Terms and Conditions.
- Office of Finance—Board Appointments.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

William W. Ginsberg,

Managing Director.

[FR Doc. 98–25246 Filed 9–17–98; 10:45 am]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 10:00 A.M.—September 21, 1998.

PLACE: 800 North Capitol Street, N.W.—Room 904, Washington, D.C.

STATUS: Closed.

MATTER(S) TO BE CONSIDERED: 1. Carrier Pricing Practices in the Transpacific Trades.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 98–25316 Filed 9–17–98; 2:55 pm]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0304]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 21, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

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: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910–0001—Reinstatement)

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the act is effective with respect to such drug. Section 505(b) and (j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314), who apply for approval of a NDA in order to market or to continue to market a drug.

The following sections in part 314 set forth the specific format and content requirements for NDA's.

Section 314.50(a) requires that an application form (Form FDA 356h) includes basic introductory information about the drug as well as a checklist of enclosures. (Section 314.50(a) is already approved by OMB under 0910–0338 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information as described under § 314.53 be submitted with the application. (Section 314.50(h) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(i) requires that patent certification information be submitted in 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing. (Section 314.50(i) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application. (Section 314.50(j) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by 505(b)(2) applicants and that certain content and notification procedures be followed. (Section 314.52 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (Section 314.80(c)(1) and (c)(2) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.80(c)(1)(i) and (c)(1)(iii) establish recordkeeping requirements for reports of postmarketing adverse drug experiences. (Sections 314.80(c)(1)(i) and (c)(1)(iii) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(1) requires that field alert reports be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253). (Section 314.81(b)(3)(i) is already approved by OMB in ''Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics For Human Use,'' which published in the **Federal Register** of October 24, 1997 (62 FR 55408), and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (Section 314.81(b)(3)(iii) is already approved by OMB under 0910–0045 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection hour burden estimate for NDA waiver requests is included in Table 1 of this document under estimates for §§ 314.50, 314.60, 314.70, and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30. (Section 314.93 is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

The following sections in part 314 set forth requirements when submitting an abbreviated new drug application (ANDA).

Section 314.94(a) and (d) requires that an ANDA contain the following and information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; and patent certification.

Section 314.95 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by ANDA applicants. (Section 314.95 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.96 sets forth requirements for amendments to an unapproved application.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA's approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements. (Section 314.98(a) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.98(c) requires other postmarketing reports: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection hour burden estimate for field alert reports is included in Table 1 of this document under § 314.81(b)(1); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection hour burden estimate for ANDA waiver requests is included in Table 1 of this document under estimates for §§ 314.94(a) and (d), 314.96, and 314.97.)

Section 314.101(a)(3) states that, if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c)(4) requires notice to FDA by ANDA or 505(b)(2) application holders of any legal action concerning patent infringement. (Section 314.107(c)(4) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(e)(2)(iv) requires that an applicant submit a copy of the entry of the order or judgement to FDA within 10 working days of a final judgement. (Section 314.107(e)(2)(iv) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(f) requires that an ANDA or 505(b)(2) applicants notify FDA of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any

legal action for patent infringement. The patent owner or approved application holder who is an exclusive patent licensee must submit to FDA a waiver that waives the opportunity to file a legal action for patent infringement. (Section 314.107(f) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(3) and (a)(4) requires after receipt of an FDA approvable letter, an applicant request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(a)(3) and (a)(4) is included under the parts 10 through 16 (21 CFR part 10 through 16) hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(5) requires that, after receipt of an approvable letter, an applicant notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) provides that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(b) is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(3) requires that an applicant request within 10 days after receipt of a not approvable letter, an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.120(a)(3) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.120, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(5) requires that an applicant notify FDA within 10 days after receipt of a not approvable letter, that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.122(a) states that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (Section 314.122(a) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (Section 314.122(d) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (Section 314.126(c) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(a) and (b) set forth requirements for the withdrawal of and approval of an ANDA and the applicant's opportunity for a hearing and submission of comments. (Section 314.151(a) and (b) is included under the parts 10 through 16 hearing regulation, in accordance with § 314.201, and it is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. (Section 314.151(c) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.152(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (Section 314.152(b) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.161(b) and (e) set forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (Section 314.161(b) and (e) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. (Section 314.200(c), (d), and (e) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(f) requires that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (Section 314.200(f) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(g), requires that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (Section 314.200(g) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (Section 314.430 is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(c) and (e) requires that, if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (Section 314.530(c) and (e) is included under the parts 10 through 16 hearing regulation, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (Section 314.530(f) is already approved by OMB under 0910–0194 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.550 requires that applicants submit all promotional materials to FDA for consideration during the preapproval review period. (The burden hours required for

§§ 314.550 are reported and approved under OMB control number 0910–0376, which published in the **Federal Register** at 62 FR 55408 and is not included in the hour burden estimates in Table 1 of this document.)

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314, to obtain approval of a new drug or antibiotic drug, and any person who owns an approved application or abbreviated application.

In the **Federal Register** of May 28, 1998 (63 FR 29229), the agency requested comments on the proposed collection of information. No comments were received.

Elsewhere in this issue of the **Federal Register**, the agency has published a Notice of Availability of a Draft Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications in accordance with section 118 of the FDA Modernization Act. The goal of the draft guidance is to reduce the submission burden of applicants where appropriate. The estimated PRA reporting burden for § 314.50 reflects an anticipated reduction of 300 hours in burden.

Based on the information provided by the pharmaceutical industry for the number of hours per response, on FDA's estimate of the reduction in reporting resulting from the draft guidance for submitting abbreviated reports and synopses for marketing applications, and on FDA's prior experience with respondents, the number of responses per respondent, and the number of total annual responses, FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section [Form Number]	No. of Respondents	No. of Responses per Respondents	Total Annual Responses	Hours per Response	Total Hours
314.50 (b), (c), (d), (e), (f), and (k)	83	1.49	124	1,300	161,200
314.54	4	1.25	5	300	1,500
314.60	144	16.89	2,432	80	194,560
314.65	18	1.28	23	2	46
314.70 and 314.71	418	5.33	2,229	300	668,700
314.72	59	2.17	128	2	256
314.81(b)(1) [3331]	140	5	700	48	33,600
314.81(b)(2) [2252]	269	9.06	2,438	40	97,520
314.94(a) and (d)	117	3.96	464	480	222,720
314.96	315	12.43	3,915	80	313,200
314.97	152	19.74	3,000	80	240,000
314.98(c) [2252]	265	17.17	4,551	40	182,040
314.99(a)	46	13.04	600	2	1,200
314.110(a)(5)	55	1.13	62	8	496
314.120(a)(5)	26	1.12	29	8	232
314.420	450	1.11	500	8	4,000
Total					2,121,270

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

Dated: September 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25142 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0159]

International Conference on Harmonisation; Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document provides broad guidance on appropriate standards for the derivation and characterization of cell substrates used in the production of biotechnological/biological products and recommends information in these areas that should be presented in marketing applications.

DATES: Effective September 21, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

Regarding 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