provided by States, Federal agencies contacted, and an indication of the type(s) of information returned, will be stored on a history tape and in hard copy for five years and then destroyed.

Records of information provided by financial institutions for the purpose of facilitating matches will be maintained only long enough to communicate the information to the appropriate State agent. Thereafter, the information provided will be destroyed. However, records pertaining to the disclosures, which include information provided by States, Federal agencies contacted, and an indication of the type(s) of information returned, will be stored on a history tape and in hard copy for five years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Program Operations, Office of Child Support Enforcement Administration for Children and Families, 370 L'Enfant Promenade, SW, 4th Floor East, Washington, DC 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager at the address listed above. The request must indicate whether the information concerns the requestor or someone else. It must also be notarized and contain the individual's full name and address. Additional information, such as Social Security Number, date of birth or mother's maiden name, may be requested by the system manager in order to distinguish between individuals having the same or similar names.

RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records. Requesters should provide a detailed description of the records contents they are seeking.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under system manager above, and identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely or irrelevant.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State and from multistate financial institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 99–5584 Filed 3–5–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0453]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices: Third-Party Review Program Under the U.S./EC MRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices: Third-Party Review Program Under the U.S./EC MRA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 14, 1998 (63 FR 68773), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0378. The approval expires on February 28, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5518 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0645]

Medical Device Warning Letter Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is initiating a pilot program involving the medical device industry that is a continuation of the ''medical device industry initiatives.'' This pilot concerns the issuance of warning letters for quality system, premarket notification submission (510(k)), and labeling violations. This pilot is intended to optimize resource utilization, enhance communication between industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The pilot includes eligibility criteria and procedures for the issuance of warning letters.

EFFECTIVE DATES: Initiation date March 29, 1999. Termination date September 8, 2000.

ADDRESSES: Submit written comments on the pilot 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 docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the pilot.

FOR FURTHER INFORMATION CONTACT:

Device quality system warning letter pilot: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

Premarket notification (510(k)) and labeling warning letter pilot: Chester T. Reynolds, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4618, FAX 301–594–4610.

SUPPLEMENTARY INFORMATION:

I. Background

During FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. After considering these issues, the agency is initiating a pilot program that will last

for 18 months, and then be formally evaluated. The pilot includes procedures for the issuance of warning letters for quality system (21 CFR part 820), 510(k) (21 CFR part 807, subpart E) and labeling (e.g., 21 CFR part 800, subpart B; part 801, and part 809, subparts B and C) violations. This pilot is currently restricted to the medical device industry and is a continuation of the medical device industry initiatives.

The purpose of this pilot is to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. Implementation of this pilot will not impact on violative situations where enforcement action is necessary to protect the public health.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). In the **Federal Register** of August 27, 1998 (63 FR 45821), FDA published a notice of availability of the draft pilot as a Level 1 guidance document consistent with GGP's. FDA received comments on the draft from a medical device trade association and three individual firms. FDA evaluated these comments and made revisions to the guidance as appropriate.

The medical device warning letter pilot is being issued as a guidance document and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. The pilot consists of two parts that are described below:

I. Device Quality System Warning Letter Pilot

Effective Dates: Initiation date March 29, 1999. Termination date September 8, 2000.

This pilot is restricted to the medical device industry and is a continuation of the medical device industry initiatives.

Following a domestic device quality system inspection which finds current good manufacturing practice (CGMP) deficiencies (situation 1, compliance program (CP) 7382.830–part V) that warrant a warning letter, the establishment is to be given 15 working days to respond from the issuance date of the list of inspectional observations (FDA–483). If the firm's written response to the FDA–483 is deemed to be satisfactory by the district office, then a warning letter should not be issued.

The device quality system warning letter pilot does not apply to:

1. Nonquality system inspections such as mammography, radiological health, and bioresearch inspections;
2. Establishments that manufacture devices as well as other FDA regulated products;
3. Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);
4. Recidivous establishments as defined in CP 7382.830;
5. Any inspection that uncovers CGMP, premarket notification submission (510(k)), or labeling deficiencies that may cause serious adverse health consequences;[1]
6. A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;
7. Any inspection that discloses other significant device violations (e.g. medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action; or
8. A situation where the firm's management failed to make promptly available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

If the district is essentially satisfied with the written response to the FDA–483 but needs further clarification, it may seek additional information via untitled correspondence, meetings, or telephone.

If the firm fails to respond to the FDA–483, a warning letter should be sent to the establishment once the 15 working day period has expired.

If the district receives a response to the FDA–483 within 15 working days, the district has 15 working days from the receipt date to determine whether the response is satisfactory.

If it is necessary for the district to consult with the Center for Devices and Radiological Health's Office of Compliance for technical assistance, the latter office has 15 working days to respond to the district and then the district has 15 working days, following receipt of the Center's response, to respond to the establishment. In this situation, the agency should not exceed 30 working days from the receipt date of the written response to the FDA–483.

If the written response to the FDA–483 is determined to be unsatisfactory, the district should send a warning letter to the establishment.

When no warning letter is issued by the district office due to the firm's satisfactory written response, the postinspectional notification letter (see attachment 1 of this document) should be sent to the establishment. The inspection should be classified as voluntary action indicated (VAI) and the profile should be designated as acceptable.

When no warning letter is issued, following a satisfactory written response, and the next inspection discloses situation 1 CGMP deficiencies, then FDA personnel should proceed as if a warning letter had been issued for the previous inspection and consider appropriate enforcement action. (See the graphic for the device quality system warning letter pilot as attachment 2 and table 1 for attachment 3.)

This pilot will be evaluated by FDA at the end of the 18-month period.

Copies of all domestic warning letters that include a device CGMP adulteration charge (section 501(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(h))) for inspections that are initiated between March 29, 1999, and September 8, 2000, should be forwarded by the districts to the Division of Compliance Management and Operations (DCMO)/Office of Enforcement (OE) (HFC–210) with a cover page. (See attachment 4 for a copy of this cover page.)

When warning letters are not issued for situation 1 CGMP deficiencies under this pilot, copies of the postinspectional notification letters issued for the inspections initiated between the above dates should be sent to Jeffrey B. Governale, Division of Compliance Policy (DCP)/OE (HFC–230) by the districts.

Any questions concerning this pilot should be directed to Jeffrey B. Governale via telephone (301–827–0411), facsimile (301–827–0482), or electronic mail (Jeffrey Governale@OE@FDAORAHQ).

Attachments, as stated:

Attachment 1—Model Postinspectional Notification Letter for Device Quality System Warning Letter Pilot

[Name and title of most responsible individual]

[Establishment's name and address]

Dear _____ :

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the following devices:

[list devices and their profile classes]

At the end of the inspection, the FDA investigator left a list of inspectional observations (FDA–483) at your firm. We have received your firm's written response, dated [date] to that FDA–483. Copies of this response and the FDA–483 are enclosed.

While this inspection found deficiencies of your quality system that would warrant a warning letter if not corrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings. The agency is relying on your commitment regarding corrective actions and, should we later observe that the deviations from the quality system regulation have not been remedied, future regulatory action (e.g., seizure, injunction and civil penalties) may be taken without further notice.

Based upon your corrective action, the deficiencies noted during FDA's inspection will not affect applicable pending premarket submissions or export certificates for devices manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts.

There may be other devices and operations of your firm for which the conclusions from

[1] ''Serious adverse health consequences'' are to have the same meaning as ''serious injury,'' which is defined in § 803.3(aa)(1) (21 CFR 803.3(aa)(1)).

this inspection are not applicable. The agency may separately inspect your firm's facilities to address the quality system regulation in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to assure you are continuing to maintain conformance with the quality system regulation.

For further information, please contact the following individual at this office:

[name and telephone number]

Sincerely,

District Director

_____ District Office

Enclosures

bcc:

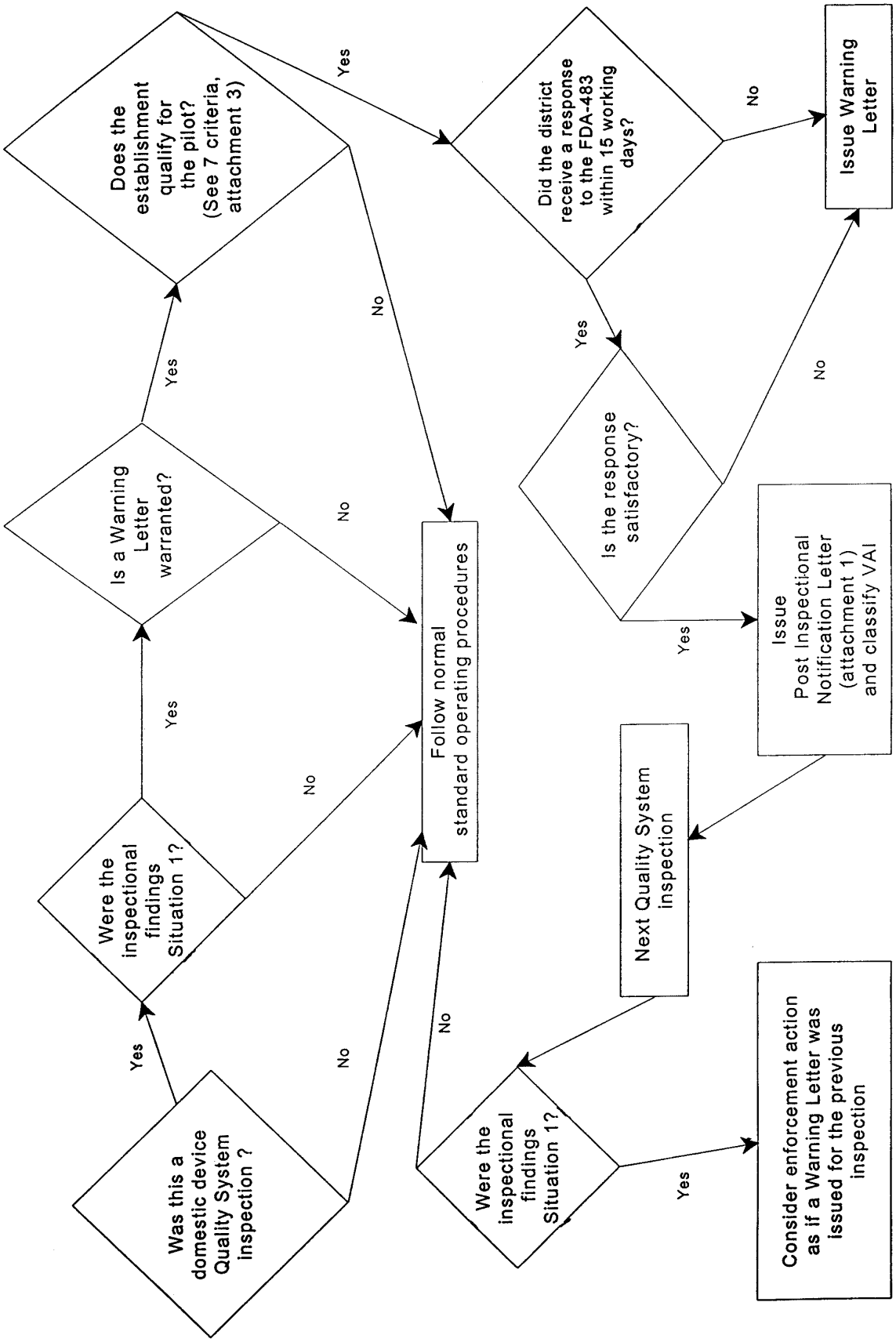
HFC–230 (Governale)

[district office internal distribution]

BILLING CODE 4160–01–F

Attachment 2

Device Quality System Warning Letter Pilot



BILLING CODE 4160–01–C

Attachment 3—Device Quality System Warning Letter Pilot

Important: If one or more of your answers to any of the questions are different than those found in the answer column of Table 1, then this pilot does *not* apply to your situation. You should follow FDA's normal standard operating procedures instead.

TABLE 1

Number	Question	Answer
1	In addition to devices, does the establishment manufacture other FDA regulated products?	No
2	Does the establishment manufacture devices that are regulated by CBER?	No
3	Is the establishment a recidivous firm per CP 7382.830?	No
4	Did the inspection uncover CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences?	No
5	Was this a compliance followup inspection to a warning letter or regulatory action for quality system, 510(k), or labeling violations?	No
6	Did the inspection disclose other significant device violations in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action?	No
7	Did the firm's management make promptly available to FDA all required information that was requested?	Yes

Attachment 4—Cover Page for the Device Quality System Warning Letter Pilot

To: FDA/ORA/OE/DCMO (HFC–210)

(mailing address: 5600 Fishers Lane, Rockville, MD 20857–001)

From: _____

_____District (HFR–_____)

Establishment's name and address:

Date inspection was initiated:

(This cover page should be attached to each warning letter that includes a device CGMP adulteration charge (under section 501(h) of the act). Please refer to the device quality system warning letter pilot before filling out this cover page.)

The attached warning letter was issued for device CGMP deficiencies. Please check all of the following statements that apply:

_____ The establishment did not respond to the FDA–483 within 15 working days.

_____ The establishment provided an unsatisfactory response to the FDA–483 within 15 working days.

_____ The establishment manufactures devices as well as other FDA regulated products.

_____ The establishment manufactures devices that are regulated by CBER.

_____ The inspection uncovered CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences.

_____ The inspection disclosed other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action.

_____ The firm's management failed to make promptly available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

Please record any comments that the district may have concerning this pilot on the back of this cover page.

II. Premarket Notification (510(k)) and Labeling Warning Letter Pilot

Effective Dates: Initiation date March 29, 1999. Termination date September 8, 2000.

A. Background

The impetus for this pilot has its origins in FDA grassroots meetings with the medical device industry. During these meetings, warning letters, for both premarket notification submission (510(k)) and labeling violations, were identified as topics for discussion. Manufacturers contend that:

1. They are often unaware of the agency's concerns about 510(k) and labeling issues until they receive a warning letter;

2. Information about these concerns is often available at the time of the inspection; and

3. If notified during the inspection, manufacturers would have an opportunity to respond, and perhaps resolve, the concerns identified by the investigators.

Consequently, this pilot has been developed in response to the device industry's concerns. The purpose of this pilot is to determine whether notifying firms about 510(k) and labeling issues, in lieu of a warning letter, will result in the efficient resolution of the issues.

B. Pilot Procedures

The 510(k) and labeling warning letter pilot does not apply to the following situations:

1. Advertising and promotion issues;

2. Establishments that manufacture devices as well as other FDA regulated products;

3. Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);

4. Any inspection that uncovers CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences;[2]

5. A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;

6. Any inspection that discloses other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action;

7. A situation where the firm's management failed to make promptly available to FDA personnel all requested information and records required by regulations or laws enforced by FDA;

8. Devices that were never cleared by FDA with a 510(k) and were not exempted from this requirement (§ 807.81(a)(1) or (a)(2)) (21 CFR 807.81(a)(1) or (a)(2));

9. A major change or modification in the intended use of the device (§ 807.81(a)(3)(ii)); or

10. Electronic products that emit radiation as defined in 21 CFR 1000.3.

Domestic device inspection reports, with endorsements, that identify possible 510(k) violations of § 807.81(a)(3)(i) (a change or modification in the device that could significantly affect the safety or effectiveness of the device) and/or possible labeling violations should be forwarded to the Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), HFZ–306. If CDRH believes that a warning letter situation exits, OC will notify the establishment via an untitled letter within 30 working days. The untitled letter will inform the establishment of the need to correct the violation by submitting either a new 510(k) or an appropriate labeling change. CDRH will send a copy of this letter to the home district. If a warning letter or untitled letter is not warranted, OC will notify the district by memorandum, facsimile, or electronic mail. The district will inform the establishment, in writing, that no correction is required.

Firms will have 15 working days from the date of a CDRH untitled letter to respond. CDRH will have 30 working days to evaluate the firm's response. An exception to this timeframe may occur if CDRH has to consult with the district and/or the firm. If CDRH

[2] ''Serious adverse health consequences'' are to have the same meaning as ''serious injury,'' which is defined in § 803.3(aa)(1).

determines that a firm's response is satisfactory, a warning letter should not be issued. If CDRH is essentially satisfied with the firm's response but needs further clarification, it may seek additional information via telephone or untitled correspondence.

If a firm fails to respond to CDRH's untitled letter, a warning letter should be sent to the establishment by CDRH when the 15 working day timeframe has expired. If CDRH receives a response to the untitled letter within 15 working days, CDRH has 30 working days from the receipt date to determine whether the response is satisfactory. If the written response is determined to be unsatisfactory, CDRH should send a warning letter to the establishment.

When no warning letter is issued by CDRH due to a firm's satisfactory written response, a postinspectional notification letter should be sent by CDRH to the establishment, with a copy to the home district, which includes the following language:

''While this inspection found deficiencies concerning [insert 'premarket notification (510(k)),' 'labeling,' or both as appropriate] that would warrant a warning letter if uncorrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings. The agency is relying on your commitment regarding corrective actions and, should we later observe that these deficiencies have not been remedied, future regulatory action (e.g. seizure, injunction and civil penalties) may be taken without further notice.''

When a CDRH decision is made not to send a warning letter due to a satisfactory written response from the firm, the district should classify the inspection as VAI for the labeling or 510(k) issues.

When no warning letter is issued, as described previously, and the next inspection of the firm discloses significant 510(k) and/or labeling deficiencies, then FDA personnel should proceed as if a warning letter had been issued for the previous inspection and consider appropriate enforcement action.

C. Administrative

Copies of all warning letters will be forwarded to the Division of Compliance Management and Operations (DCMO), Office of Enforcement (OE) (HFC–210). When warning letters are not issued for 510(k) or labeling deficiencies under this pilot, copies of the postinspectional notification letters issued for inspections that are initiated between March 29, 1999, and September 8, 2000, should be sent to Jeffrey B. Governale, Division of Compliance Policy (DCP)/OE, HFC–230.

CDRH's OC will monitor the warning and postinspectional notification letters and evaluate the pilot 18 months after it begins. Any questions about this pilot should be directed to Chester T. Reynolds, OC/CDRH, HFZ–300.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this pilot program. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments will be considered in determining whether to revise, revoke, or adopt this pilot program on a permanent basis. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

A copy of the pilot may also be downloaded to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs (ORA) and the CDRH home pages include the pilot and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'', respectively. The pilot will be available on the compliance references or program areas/compliance information pages for ORA and CDRH, respectively.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5523 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0964]

''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product.'' The guidance document is intended to provide guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for a biological in vitro diagnostic product. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product.'' The guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance document announced in this notice supersedes the draft guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment