17 CFR Part 140

Change in Titles of Personnel

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule; correction.

SUMMARY: CFTC is correcting an error in a change to titles of personnel previously published in the Federal Register on May 13, 1996, (61 FR 21955). The original document contained an erroneous paragraph reference.

EFFECTIVE DATE: May 13, 1996.

FOR FURTHER INFORMATION CONTACT: Stacy Dean Yochum, Counsel to the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St. NW., Washington, DC 20581, (202) 418–5157.

Correction

In the final rule FR Doc. 96–11923, beginning on page 21954 in the Federal Register issue of May 13, 1996, make the following correction:

On page 21955, in the first column, in amendment 4. to § 140.735–8, the reference to ''paragraph (a)(3)'' is corrected to read ''paragraph (b)(3).''

Dated: March 14, 1997.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–6971 Filed 3–19–97; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADA's) from Biocraft Laboratories, Inc., to Teva Pharmaceuticals USA.

EFFECTIVE DATE: March 20, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA's 65–492 (amoxicillin trihydrate tablets) and 65–495 (amoxicillin trihydrate for oral suspension) to Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960. Accordingly, the agency is amending the regulations in 21 CFR 520.88b and 520.88f to reflect the transfer of ownership.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.88b [Amended]

2. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing the number ''000332'' and adding in its place ''000093''.

§ 520.88f [Amended]

3. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing the number ''000332'' and adding in its place ''000093''.

Dated: March 11, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–7002 Filed 3–19–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 803 and 804

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Medical Device Reporting; Annual Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device manufacturer and distributor adverse event certification regulations. The revised certification requirements allow manufacturers and distributors to designate more than one certifying official, who would each sign a certification statement for his or her identified organizational component or site; amend the certification statement to minimize concerns relating to liability from unintentional reporting errors; and indicate that the certifying official is making the certification statements, to the best of his/her knowledge and belief. This action is being taken to help FDA carry out its public health protection responsibilities relating to medical devices. This action provides reporting entities with greater flexibility in the certification process while reducing the regulatory burden.

DATES: Effective May 19, 1997. Submit written comments on the information collection requirements by April 21, 1997.

ADDRESSES: Submit written comments on the final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION:

I. Background

Section 519(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(d)) provides that each manufacturer, importer, and distributor shall certify that they did file a certain number of medical device reports (MDR's) in the previous 12 months or they did not file any MDR's. Distribution certification regulations implementing this statutory provision became effective on May 28, 1992, when requirements relating to distributor reporting that were proposed in the Federal Register of November 26, 1991 (56 FR 60024), became final by operation of law. In the Federal Register of December 11, 1995 (60 FR 63578), FDA published a final rule similar to the distributor certification provisions, that required manufacturers to submit certification statements (§ 803.57 (21 CFR 803.57)) (hereinafter referred to as the December 1995 final rule). Distributors and manufacturers were required to certify that they filed reports for all reportable events required under

the rule for the previous 12 months or to certify that they did not receive any reportable events during the reporting period (§ 803.57 and 804.30 (21 CFR 804.30). The December 1995 final rule required certification to be made by the company's president, chief executive officer (C.E.O.), the U.S. designated agent, or other official most directly responsible for the firm's operations. The effective date of this regulation was to be April 11, 1996. In the Federal Register of April 11, 1996 (61 FR 16043), FDA extended the effective date to July 31, 1996.

Subsequent to the issuance of the December 1995 final rule, industry representatives objected to the corporate status of the person required to certify as well as the content of the certification statement itself. On April 19, May 23, and June 13, 1996, FDA held meetings with the Health Industry Manufacturers Association and several industry representatives. During these meetings, industry objected to requiring the C.E.O. or president to certify, because, especially in a large company, that person would not be familiar with the details of the MDR reporting program. Industry representatives also objected to the requirement that they certify that they filed reports for all reportable events during the reporting period. Industry representatives asserted that this requirement was not supported by the language of section 519(d) of the act. Moreover, industry representatives asserted that it would be impossible to certify that they submitted all ''reportable'' events because that would be a subjective conclusion and there could be honest disagreements between FDA and the manufacturer as to whether a particular event was a ''reportable'' event. Accordingly, industry representatives viewed the subjective nature of the certification statement as placing corporate officials in an untenable position with respect to their liability.

In response to industry concerns, the agency reviewed its position in light of the statutory language and legislative history. In the Federal Register of July 23, 1996 (61 FR 38346), the agency stayed the effective date of the certification requirement of the December 1995 final rule. In that same issue of the Federal Register (61 FR 63548), the agency reproposed a new certification requirement.

As discussed more fully in the preamble of the July 23, 1996, proposal, and in response to the comments below, the legislative history of section 519(d) of the act shows that the intent of Congress was to improve MDR efficiency by making firms more aware of their reporting obligations under MDR. The preamble of the proposed rule also stated that although FDA believed that the certification provision in its December 1995 final rule was within the scope of the statutory authority provided by section 519(d) of the act, FDA believed that the proposed modified certification provision would address the concerns expressed about the existing certification provisions and still meet the intent of section 519(d) of the act.

The July 23, 1996, proposed rule provided that the firms would be required to designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. The proposal also provided that, based upon its organizational structure, a firm may designate more than one certifying official, each of whom would sign a certification statement for his/her identified organizational component or site. The proposal would have required the individual certifying for the firm to state that: (1) He/she has read the requirements of the MDR regulation; (2) the firm has established a system to implement MDR reporting; and (3) following the procedures of its MDR reporting system, the firm submitted a specified number of reports, or no reports, during the certification period.

After reviewing the comments discussed below, FDA is now issuing a final rule based upon the proposed certification requirements, amended only by the additional statement that the certifying official is making the certification statements ''to the best of [his/her] knowledge and belief.'' In framing the certification in this way, the agency has attempted to eliminate industry's concern about potential liability for inadvertent errors, by requiring certification of objective statements to the best of the certifier's knowledge. It is a factual matter as to whether the certifier has read the MDR regulation, whether the company has established a system to implement those regulations, and how many MDR's the company submitted to FDA as a result of following that system. At the same time, FDA believes that this certification statement is a reasonable requirement that will achieve the intent of section 519(d) of the act by making reporters more aware of their MDR obligation, and will result in corporate management taking active responsibility for its MDR program. To implement section 519(d) of the act, FDA believes the regulation is reasonable in requiring a responsible company official to certify to the best of his/her knowledge and belief, that he/she has read the MDR regulation, that there is a system in place to implement those regulations, and that a specific number of reports were submitted under that system.

The agency is also taking this opportunity to stress the importance of certification by all firms covered under this rule, and by all sites or organizational components of such firms, if more than one certifying official is designated. The agency recognizes that, depending upon the organizational structure of a medical device firm, one certifying official may not be able to oversee or have complete knowledge of the operation of all components or sites owned by the firm. For this reason, the agency proposed that, in this circumstance, the firm may designate more than one certifying official, who will each sign a certification statement pertaining to his/her respective identified components or sites. The agency is taking this opportunity to clarify that, if the firm designates more than one certifying official, all organizational components or sites must be assigned to an appropriate certifying official, so that all sites and components of a firm are covered under a certification statement. The final rule has been modified to clarify this concept.

II. Summary of Comments

1. The agency received five comments on the July 23, 1996, proposed rule, submitted by manufacturers, industry representatives, and industry associations. Four of these comments were in strong support of the proposed changes. These comments praised the agency for its responsiveness and its appreciation of the diversity of the medical device industry. Specifically, these comments approved of the designation of responsible certifying official or officials who would have the most direct knowledge of the adverse event reporting process. Although these comments also noted that there may still be some question as to whether the certification statement exceeds the statutory requirement, because these comments found the certification statement to be reasonable, the comments requested only one change to the certification statement—the inclusion of the words ''to the best of my knowledge.''

The agency agrees with these comments and has modified the certification statement accordingly. The agency has already acknowledged that certifications should be made to the best knowledge of the certifier. In the April 11, 1996, Federal Register document announcing the Office of Management and Budget (OMB) approval of MDR

reporting forms, and extending the effective date of the MDR final rule, FDA concluded it would be reasonable to include the qualifying phrase ''to the best of my knowledge'' in this type of certification statement (see 61 FR 16043 at 16045). Likewise, in the certification statement submitted as part of a premarket notification, the agency has included language stating that the statement is made to the best of the certifier's knowledge (see 21 CFR 807.94(a)). Accordingly, the MDR certification statement, as modified in this final rule, now contains language that ''the certification is made to the best of the certifying official's knowledge and belief.''

2. The remaining comment believed the proposed certification statement was not reasonable. This comment maintained that the agency does not have statutory authority to require any more than certification of the number of reports submitted. Furthermore, this comment found the proposed certification statement to be ambiguous and requested clarification of several terms and concepts.

Specifically, this comment questioned whether, when the certifying official states that he/she has ''read the requirements of the MDR regulation,'' this would be interpreted to mean that the official is knowledgeable and understanding of the regulation and associated guidance documents. The comment objected to this interpretation because the certifying official would be at risk if he/she had read the regulation, but did not understand all the finer points of the intent or requirements of the regulation or supporting documents.

Likewise, this comment questioned whether the certification statement, which states that ''the firm has established a system to implement medical device reporting,'' may be interpreted by the agency to impute that such system is ''adequate,'' and thereby put the certifying official at risk, as one reporting error would render the reporting system inadequate. According to the comment, the same error in reporting would put the certifying official at risk when he/she certifies that ''following the procedures of its medical device reporting system'' certain reports were filed. This comment also expressed concern that the certifying official may be at risk if the agency disagrees with the manufacturer's determination that certain events are not reportable. The comment then suggested alternative wording to the certification statement designed to obviate these concerns.

The agency disagrees with the comment that the certification statements are ambiguous and create the risks described above to the certifier. The certification requirement simply requires the certifier to attest to certain facts, i.e., that he/she has read the MDR reporting requirements, that the firm has established MDR reporting systems to implement those requirements, and that those procedures were followed in submitting the MDR's. Certification to these facts does not add any additional liability to the certifier for reporting errors. However, as noted above, to alleviate concern that the proposed certification statements may subject certifiers to liability for inadvertent or good faith errors, FDA has adopted the suggestion of several comments by qualifying the certification with the statement that ''the certification is made to the best of the certifying official's knowledge and belief.'' FDA believes that this change appropriately addresses these concerns.

FDA also does not agree that the revised final regulation is beyond the statutory authority provided under section 519(d) of the act. Section 519(d) of the act requires that each manufacturer, importer, and distributor annually certify the number of MDR's or that no reports were filed. FDA disagrees with the comments' interpretation that this provision limits FDA's authority to issue a regulation to require certification solely of the number of MDR's filed or that no MDR's were filed. FDA's final regulation, which requires that the person filing the certification has read the MDR reporting requirements, that the firm has established a system to implement MDR reporting requirements, and that following these procedures a certain number of MDR's were filed or that no MDR's were filed, is well within the ambit of section 519(d) of the act.

The legislative history of section 519(d) of the act states that Congress included this provision on the recommendation of the General Accounting Office (GAO) as an important means of increasing the effectiveness of the MDR system (see H. Rept. 808, 101st Cong., 2d sess., 23 (1990); S. Rept. 513, 101st Cong., 2d sess. 26 (1990)). The GAO report noted that certain information indicated that a third of establishments inspected were not even aware that the MDR reporting requirements existed (1989 GAO Report entitled ''FDA's Implementation of the MDR Regulation,'' p. 4). The GAO report recommended certification to ensure that all manufacturers and importers be made aware of their obligation to submit MDR's and to identify those firms that were not aware of their obligation (Id. pp. 5 and 69).

The legislative history of section 519(d) of the act indicates that Congress' clear intent in requiring certification was to ensure that those required to report MDR's were aware of those requirements. FDA does not believe that requiring certification of solely the number of MDR's filed or that no MDR's were filed, adequately achieves this purpose. The final regulation ensures that firms are aware of the requirements by requiring firms to certify that a responsible person has read the requirements, the firm has established a system to implement these requirements, and this system was followed in submitting MDR's. In that the final regulation is consistent with the intent of Congress to make reporters aware of their obligations, FDA believes that the final regulation is fully within the ambit of section 519(d) of the act.

III. Implementation

Under final §§ 803.57(a) and 804.30(a), the agency has retained the schedule for submitting certification as established by the December 1995 final rule. The schedule for submitting annual certifications shall correspond with the schedule provided in § 807.21 (21 CFR 807.21(a)) for firm registrations, and must be followed by all firms required to certify regardless of whether the firm is required to register. Under this schedule, annual certifications will be due in either April, July, September, or December, depending on the first letter of the name of the owner or operator of the reporting firm. FDA intends that the first group of certifications will be due at the same time the first annual registrations would be due, at least 6 months after the effective date of the final rule.

According to this schedule, the first group of annual certifications will be due in April 1998, for firms whose owner or operator name begins with the letters A–E. This first group of certifications will certify to MDR's submitted between the effective date of this rule and March 1998. The second group of annual certifications will be due in July 1998, for firms whose owner or operator name begins with the letters F–M. This group of certifications will certify to MDR's submitted between the effective date of this rule and June 1998. The third group of annual certifications will be due in September 1998, for firms whose owner or operator name begins with the letters N–R, and will certify to MDR's submitted between the effective date of this rule and August 1998. The final group in this series of annual certifications will be due in December 1998, for firms whose owner or operator name begins with the letters S–Z, and

will certify to MDR's submitted between the effective date of this rule and November 1998.

After the initial certifications, firms shall submit certification reports annually, certifying to the MDR's submitted in the previous 12-month period ending 1 month prior to the month the certification is due, consistent with the schedule provided in § 807.21(a).

IV. Analysis of Impacts

FDA has examined the economic impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity. The agency believes that this rule is consistent with the principles identified in the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule applies to all medical device manufacturers and distributors whose devices are sold in the United States. The rule relieves two regulatory burdens. It allows the certification statement to be signed by the person most familiar with the MDR program, not necessarily the president or C.E.O. It also changes the certification statement to minimize the industry's concern about the possibility of liability as a result of an unintended mistake in reporting. Therefore, under the Regulatory Flexibility Act, the Commissioner of Food and Drugs certifies that this final rule does not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

This rule contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections are shown below along with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reporting and recordkeeping requirements for user facilities, distributors, and manufacturers of medical devices under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992 (General Requirements).

Description: This regulation amends regulations regarding device manufacturer and distributor reporting of deaths, serious injuries, and certain malfunctions related to medical devices. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on reporting entities. This rule amends information collection requirements which have been approved under OMB No. 0910–0059.

Description of Respondents: Businesses or other for profit organizations, Federal, State, and local Governments.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.57	12,000	1	12,000	1	12,000
804.30	8,200	1	8,200	1	8,200
Total	20,200	.....	20,200	.....	20,200

There are no capital costs or operating and maintenance costs expected as a result of this rule.

Under OMB No. 0910–0059, which expires on February 28, 1999, a total of 187,610 burden hours were approved for collection of information requirements in the December 1995 final rule on medical device user facility and manufacturer reporting, certification, and registration. The 12,000 burden hours reported above in Table 1 for § 803.57 were included in the approval and therefore do not affect the total number of approved burden hours. However, the 8,200 burden hours reported in Table 1 for § 804.30 (distributor reporting) have not previously been considered in an information collection submission to OMB, and do represent an increase in the burden. Therefore, this rule would add 8,200 hours to the existing approved burden and would result in a total annual information collection burden of 195,810 hours (187,610 + 8,200 = 195,810).

In the July 23, 1996, proposed rule, the agency solicited public comments on the revised information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit written comments on the information collection requirements by April 21, 1997. Written comments on the final rule should be submitted to the Dockets Management Branch (address above).

The agency received one comment recommending an alternative format for the form associated with this reporting. Although the alternative format would not affect the reporting burden, the agency is considering the suggested modifications to the form.

List of Subjects in 21 CFR Parts 803 and 804

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803 and 804 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

2. Section 803.1 is amended by revising paragraph (a) to read as follows:

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. Additionally, user facilities and manufacturers must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

3. Section 803.57 is revised to read as follows:

§ 803.57 Annual certification.

(a) All manufacturers required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. Foreign manufacturers shall submit their certification by the date on which they would be required to register under § 807.21 of this chapter if they were domestic manufacturers. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A manufacturer may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or manufacturing sites owned by the firm. In this circumstance, the firm may designate more than one certifying official, each of whom will sign a certification statement pertaining to his/her respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the reporting site and whether the firm is a manufacturer;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for each manufacturing site covered by the certification and the number of reports submitted for devices manufactured at each site;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under this part;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the reporting site submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

(d) The name of the manufacturer and the registration number submitted under paragraph (c)(1) of this section shall be the same as the reporting site that submitted the reports required by §§ 803.52, 803.53, and 803.55. Multireporting site manufacturers who choose to certify centrally must identify the reporting sites, by registration number and name covered by the certification, and provide the information required by paragraphs (c)(2) and (c)(3) of this section for each reporting site.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

4. The authority citation for part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

5. New § 804.30 is added to read as follows:

§ 804.30 Annual certification.

(a) All distributors required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site), each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

Dated: March 12, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–7001 Filed 3–19–97; 8:45 am]

BILLING CODE 4160–01–F