SUMMARY REPORTING APPROVAL FOR ADVERSE EVENTS

DATE: July 31, 1997

TO: Manufacturers of Medical Devices Listed Below

FROM: Director, Office of Surveillance and Biometrics, CDRH, FDA

SUBJECT: SUMMARY REPORTING APPROVAL FOR ADVERSE EVENTS

The Center for Devices and Radiological Health (CDRH) has determined that many adverse events involving the devices listed below can be reported to the Food and Drug Administration (FDA) on a quarterly basis using a summary reporting format in lieu of individual event reports on FDA Form 3500A without adversely affecting FDA's ability to monitor and react to such events. Therefore, upon notification of acceptance, manufacturers of the listed devices will be granted, under the authority of 21 CFR 803.19(c), an exemption from the individual event reporting requirements of 21 CFR 803.50 and 803.52 described below for devices listed below and subject to the alternative reporting requirements contained herein.

DEVICES COVERED BY THIS EXEMPTION

The following types of medical devices are covered by this exemption:

- Intravascular (I.V.) Administration Set (Product code FPA)
- Intravascular Catheter (Product code FOZ)
- Implanted Subcutaneous Intravascular Catheter (Product code LJT)
- Mechanical/Hydraulic Incontinence Device (Product code EZY)
- Urological Catheter (Product code KOD)
- Endosseous Implant (Product code DZE)
- Diagnostic Intravascular Catheter (Product code DQO)
- Mechanical/Hydraulic Impotence Device (Product code FHW)
- Mechanical Heart Valve (Product code LWQ)
- Silicone Gel-filled Internal Inflatable Breast Prosthesis (Product code FTR)
- Saline Internal Inflatable Breast Prosthesis (Product code FWM)
- Permanent Pacemaker Electrode (Product code DTB)

TYPES OF EVENTS NOT COVERED BY THIS EXEMPTION

The following types of events are not covered by this exemption and must be reported as specified in 21 CFR 803.50 and 803.52:

- Events that require the submission of a 5-day report under the requirements of 21 CFR 803.53.
- Events where the device, other than a mechanical heart valve (product code LWQ), may have caused or contributed to a death.

- Events involving a Class III device that has been marketed under an approved PMA for less than two (2) years.
- The occurrence of multiple serious injuries as a result of a single event or device failure.
- Events associated with explosion or fire.
- Events which the manufacturer considers unusual, unique or uncommon and that would be given an evaluation conclusion code of 66-Unusual event (see Instructions for Completing Form 3500A with Coding Manual for Form 3500A, dated December 14, 1995).

BASIS FOR EXEMPTION AND REQUIREMENTS FOR ALTERNATIVE REPORTING

The events covered by this exemption and subject to alternative reporting requirements described herein are well known to the FDA and have been reported for years to the agency. CDRH has determined that it can evaluate these events and monitor their occurrence effectively and efficiently through the submission and evaluation of periodic reports summarizing events reported to the device manufacturer during the summary reporting period. This will also reduce the burden on industry and FDA that results from preparation, receipt, processing and evaluation of individual event reports submitted under 21 CFR 803.50 and 803.52.

EXEMPTION CONDITIONS

1. This exemption from the individual event reporting requirements of sections 803.50 and 803.52 and the availability of alternative summary reporting described herein applies only to those types of devices listed above under the heading "Devices Covered By This Exemption" . It does not apply to those types of events listed above under the heading "Types of Events Not Covered by This Exemption".
2. The events subject to this exemption must be reported in a summary tabular fashion to CDRH every quarter. The summary reports must contain the data listed in Attachment A. These data are a subset of the information required by 21 CFR 803.52 or could be derived from that information. An example of a summary tabular report is shown in Attachment B in order to help explain what data is to be presented in the report. A manufacturer may wish to use the example as a template for the preparation of the summary tabulation report.
3. Summary reports are due (a) January 31 for events that would otherwise be required to be reported during the preceding period between October 1 and December 31; (b) April 30 for events that would otherwise be required to be reported during the preceding period between January 1 and March 31; (c) July 31 for events that would otherwise be required to be reported during the preceding period between April 1 and June 30; and (d) October 31 for events that would otherwise be required to be reported during the preceding period between July 1 and September 30. The first summary report will be due not less than three (3) months after acceptance of this offer and will cover the period from initiation of summary reporting to the end of the quarterly reporting period. For example, a firm that initiates summary reporting on September 1 would submit the first quarterly summary report on the following January 31 to cover the four (4) month period from September 1 to December 31.
4. The manufacturer is still required to conduct an investigation and evaluation of complaints as specified in 21 CFR 803.18(e) and 803.50 and to establish and maintain MDR event files as specified in 21 CFR 803.18 for events covered by this exemption.
5. For any exempted event subject to summary reporting, if there is any remedial action involving a device that is the subject of the event, the manufacturer will have to conform to the remedial action exemption conditions contained in the "MDR Guidance Document: Remedial Action Exemption - E1996001" dated July 30, 1996. This requires the submission of at least one individual event report for the device and a Remedial Action Exemption Notification.
6. Baseline reports must be submitted as required by 21 CFR 803.55 for all device models involved in this exemption authorization. If any baseline reports were not submitted with the initial MDRs filed prior to

grants the exemption.

8. This exemption may be revoked or modified in writing if FDA determines that protection of the public health justifies the modification or a return to the requirements of 21 CFR 803.50 and 803.52 as provided in 21 CFR 803.19.
9. FDA reserves the right to request the submission of an individual event report on Form 3500A for any event(s) included in a summary report if it determines that it needs the report(s) to evaluate the event(s).

REPORTING ADDRESS

Summary reports are to be mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Information and Analysis Team (HFZ-531)
1350 Piccard Drive
Rockville, MD 20850

The envelope must be marked: "Summary Report"

NOTIFICATION OF ACCEPTANCE

Manufacturers of devices subject to this exemption may submit a notification of acceptance to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Reporting Systems Monitoring Team (HFZ-533)
1350 Piccard Drive
Rockville, MD 20850

The notification of acceptance should be submitted by September 2, 1997 and must (1) request that the manufacturer be exempt from the reporting requirements in sections 803.50 and 803.52 and consent to be subject to the alternative summary reporting conditions described herein, (2) provide the reporting site registration number, name, and address; (3) list the exempted product codes that will be summarily reported from that site; and (4) contain a proposed format for providing the summary report. If the notification of acceptance covers more than one reporting site, each reporting site must be identified in the above manner. Upon receipt of a notification of acceptance containing the information listed in items 1 through 3 above, the Office of Surveillance and Biometrics will grant the exemption in writing and send the manufacturer an exemption authorization number for each reporting site.

If you have any questions about this matter, please write to the Reporting Systems Monitoring Team (RSMT) at the above address, call 301-594-2735, or send a FAX to RSMT at 301-827-0038.

Larry Kessler, Sc.D.

FOR EACH SUMMARY REPORT

1. Name of manufacturer.
2. Registration number of the site making the report (reporting site).
3. Address of the manufacturer's reporting site (street, city, state or country, and zip code or mail code).
4. Reporting period or period of time covered by the summary report (beginning date and ending date). See item 3 under "Exemption Conditions" in memorandum.
5. Date of the summary report.
6. Number of pages in the summary report.
7. Exemption authorization number (to be provided to the manufacturer by FDA).
8. Name of the report contact (i.e., person submitting report).
9. Telephone number of contact.
10. Total number of events involving death, number of events involving serious injury, and the number of events involving device malfunction (no death or serious injury).

SEPARATELY FOR EACH DEVICE MODEL OR CATALOG NUMBER THAT WAS THE SUBJECT OF A REPORTABLE EVENT DURING THE REPORTING PERIOD

The following data must be separately provided for each device model or catalog number for which there was a reportable event during the reporting period.

1. Basic device identifier as submitted in the corresponding baseline report and whether the identifier provided is a model number, catalog number, or other type of identification number.
2. Product classification code of the device.
3. Number of events involving death for that device, number of events involving serious injury for that device, and the number of events involving device malfunction for that device (no death or serious injury).
4. The code and the number of occurrences of that code for each device problem and for each patient problem code that would have been contained in Block F10 or H11 of FDA Form 3500A if individual event reports had been submitted.
5. Number of devices not returned for analysis to the manufacturer for that device for the events included in the reporting period.
6. Number of devices evaluated by the manufacturer for events included in the reporting period.
7. The code and the number of occurrences of that code for each device evaluation result code that would have been contained in Block H6 of FDA Form 3500A if individual event reports had been submitted.
8. The code and the number of occurrences of that code for each evaluation conclusion code that would have been contained in Block H6 of FDA Form 3500A if individual event reports has been submitted.

Attachment B PDF

CDRH Home Page FDA HOME PAGE SEARCH COMMENTS

(Updated September 24, 1997)