Variance from Manufacturer Report Number Format - No. 5

DATE:	August 12, 1996
TO:	Medical Device Manufacturers
FROM:	Deputy Director, Office of Surveillance and Biometrics Center for Devices and Radiological Health, FDA
SUBJECT:	VARIANCE FROM MANUFACTURER REPORT NUMBER FORMAT

The Office of Surveillance and Biometrics, CDRH, has received several requests from manufacturers to add a new variance which would authorize a firm to use the Facility Registration Number of the reporting site in place of the Facility Registration Number of the manufacturing site of an affected device. Therefore, under the authority of 21 CFR Part 803.19(c), the following variance may be used by manufacturers when filling out form 3500A for reportable adverse medical device reports (MDRs):

VARIANCE NO. 5 (V1996005): Manufacturers who have one or more reporting site locations may use the Facility Registration Number of those sites in place of the Facility Registration Number of the manufacturing site of the affected device. In this case, the manufacturer report number requested on MedWatch form 3500A will consist of the reporting site facility registration number, the 4-digit calendar year in which the report was submitted and a 5-digit sequence number. In order to take advantage of this variance, the registration number and address of the manufacturing site of the affected device must be listed in Block G1 of the form.

If you have any questions regarding this variance, please contact the Reporting Systems Monitoring Team at: (301) 594-2735, Fax no. (301) 827-0038 or write to:

Reporting Systems Monitoring Team, HFZ-533
Division of Surveillance Systems
Office of Surveillance and Biometrics

1350 Piccard Drive
Rockville, MD 20850

Email: **rsmb@cdrh.fda.gov (mailto:rsmb@cdrh.fda.gov)**

Susan N. Gardner, Ph.D.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)