

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
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Refer to: CFN 1121788

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4012

November 13, 1996

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Frank Homa  
Ambu, Incorporated  
611 N. Hammonds Ferry Road  
Linthicum, Maryland 21090

Dear Mr. Homa:

During an inspection of your facility in Linthicum, Maryland, conducted by the Food and Drug Administration (FDA) from September 25 to 27, 1996, our investigators determined that your firm manufactures resuscitators. The resuscitators are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

The above-stated inspection revealed that the medical devices are misbranded within the meaning of Section 502(t)(2) of the FD&C Act, in that your firm failed to submit information to the FDA as required by the Medical Device Reporting (MDR) regulation, as codified in 21 CFR 803. Specifically, you failed to submit MDR reports to FDA after receiving information which reasonably suggested that your commercially distributed devices (1) may have caused or contributed to a death; or (2) malfunctioned and the device or any other device marketed by you would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. The following incidents should have been reported to FDA:

1. Ambu complaint report number 003567, Ambu Infant/Child Spur, report dated 12/19/94.  
As in the above complaint, medical personnel attempted to attach ET tube to the SPUR patient connector, but were unable to do so because the inside diameter of the SPUR connector was deformed. The patient died.

The reporter stated that he did not know the cause of the patient's death. The firm's evaluation of the returned device indicated that the problem was caused by a tight fitting mask deforming the patient connector during long term storage of the SPUR with the face mask connected (addressed in engineering change order #24). The

described problem would appear to prevent the device from performing one of its intended functions and under the circumstances described in this complaint may have caused or contributed to the patient's death. This incident should have been reported to the FDA as a death in accordance with the provisions of 21 CFR Part 803-1984.

2. Ambu complaint report number 003565, Ambu Infant/Child Spur, report dated 12/8/94.

A patient in arrest was ventilated and intubated. The medical personnel attempted to attach ET tube to the SPUR, but was not able to connect as the SPUR patient connector inside diameter was distorted. The medical personnel used another backup bag immediately, but the patient died.

Ambu, Inc.'s evaluation indicated the problem was caused by the tight fitting mask deforming the patient connector during long term storage of the SPUR with the face mask connected. As a result of your investigations of this type of complaint involving the SPUR Infant/Child deformed connectors, your firm issued an engineering change order (#24) that changed the supplier of the toddler face mask. The described problem would appear to prevent the device from performing one of its intended functions. In the absence of data establishing a causal connection between the device failure and the patient's death, and the reporter (Health Care Professional) stating that the patient's death was not connected to the performance of the medical device, this incident should have been reported to the FDA as a malfunction, as opposed to as a death, in accordance with the provisions of 21 CFR Part 803-1984.

3. Ambu complaint report number 003572, Ambu Adult Spur, report dated 2/10/95.  
A patrol unit attempted to utilize the SPUR Adult resuscitator on a patient in cardiac arrest and found the unit to be frozen in the compressed position. The officer used an alternate resuscitator, but the patient died.

The reporter (Health Care Professions) did not associate the patient's death with the failure of the device. However, the described problem would appear to prevent the device from performing one of its intended functions. This incident should have been reported to the FDA as a malfunction in accordance with the provisions of 21 CFR Part 803-1984.

4. Ambu complaint report number 003575, Ambu Infant/Child Spur, report dated 7/5/95.

This situation was similar to that described in items 1 and 2 above, but the patient did not die.

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The described problem would appear to prevent the device from performing one of its intended functions, and therefore should have been reported to the FDA as a malfunction in accordance with the provisions of 21 CFR Part 803-1984.

5. Ambu complaint report number 003576, Ambu Adult Spur, report dated 8/23/95. Medical personnel attempted to use the resuscitator on a patient in respiratory arrest, but the inlet valve was detached from the bag.

This incident would appear to result from user error and should have been reported to FDA as malfunction in accordance with the provisions of 21 CFR Part 803-1984.

6. Ambu complaint report number 003579, Ambu Mark III, report dated 6/27/96. Patient was bagged, and the bottom inlet valve came apart. The complainant reported that the bag was new, and it appeared that the inner bag was not seated properly on the flange lip. The user filed an MDR report with FDA on 7/1/96.

The described problem would appear to prevent the device from performing one of its intended functions. This incident should have been reported to the FDA as a malfunction in accordance with the provisions of 21 CFR Part 803-1984.

An MDR malfunction report is required for the events 003565, 003572, 003575, 003576, and 003579, because all five conditions listed under 21 CFR Part 803.24(d)(3)(iii)-1984 were not met. In addition, an MDR death report is required for 003567 because a patient's death has been associated with the use of the medical device identified in the complaint. FDA notes that, as reported in a letter dated October 29, 1996 from Sanjay Parikh, Technical & Regulatory Affairs Manager, Ambu, Inc. filed MDR reports on these events despite the firm's having determined that the events were not reportable.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the FD&C Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Jennifer Thomas, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201. Copies of the MDR reports for the above complaints should reference this Warning Letter and be directed to: Clarence Wilson, Consumer Safety Officer, Information Analysis Branch (HFZ-531), Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850.

Sincerely,



Kenneth C. Shelin  
District Director

cc: Ambu International A/S  
Sondre Ringvej 49  
P.O. Box 215 DK-2600  
Glostrup, Copenhagen, Denmark