

March 13, 2000

Medical Claims on Labeling and Promotional Materials of Infant Mattresses and Infant Positioners Distributed in the United States

(You are encouraged to copy and distribute this letter)

Dear Manufacturer or Own-Label Distributor:

This is to alert you that your infant mattresses and/or infant positioners are medical devices subject to FDA jurisdiction if medical claims associated with Sudden Infant Death Syndrome (SIDS) are made in the labeling of these products. Because they are medical devices when such claims are made, these products may not be legally marketed without prior FDA review. Firms who make these products or distribute them under their own label are required to register their establishment and list their devices with FDA. These firms also are subject to FDA inspection to ensure that they comply with the medical device reporting requirements and appropriate good manufacturing practices. (see definitions below)

Examples of medical claims

Here are some examples of medical claims that would cause an infant mattress or positioner to be considered a medical device:

“Reduce the risk of SIDS” “Helps prevent SIDS” “The danger of cot death can be eliminated...”
“To the extent that SIDS may be caused by a buildup of carbon dioxide in the crib mattress area, the...mattress may help reduce the risk of SIDS...”
“And while nothing is absolutely proven to prevent SIDS, this product may actually lower your baby’s risk.” “...added safety and protection against Sudden Infant Death syndrome (SIDS).”
“...a dramatic decrease in the incidence of sudden infant crib syndrome...”
“If the mattress...is correctly wrapped...There is no risk of cot death”
“...helps to reduce one phenomenon called the “sink-hole” effects recently linked to SIDS”

Options for manufacturers/distributors

If you currently have labeling that contains medical claims associated with SIDS such as those described above on any labeling of your infant mattresses and/or infant positioners, your product is subject to review by the Food and Drug Administration. If your product labeling does not contain such claims, or if you remove such claims from all your current labeling, you will not be considered a medical device manufacturer or own-label distributor and will not be required to make a premarket submission to FDA.

Obligations if you make/continue medical claims

In order for you to legally market these infant products with medical claims associated with SIDS, you must demonstrate that your product is substantially equivalent to a legally marketed product making similar claims. Or you must independently establish that your product is safe and effective for the intended use associated with reducing, preventing, or eliminating SIDs. This evidence, demonstrating either substantial equivalence or safety and effectiveness, should be submitted to FDA through a Pre-market Notification [510(k)]or Pre-market Approval (PMA) application. **Continued distribution without a 510(k) or PMA could result in FDA action.**

Immediate steps

We suggest that you review your current labeling, including any literature and internet advertising, to determine if you are making any medical claims associated with SIDS or any other medical condition or disease for your infant mattresses and/or infant positioners. After reviewing your current labeling, please advise us:

1. That your labeling does have medical claims associated with SIDS and describe the steps you are taking to change your labeling to remove the medical claims; OR
2. That your labeling does have medical claims associated with SIDS and you intend to continue marketing your products with these claims; OR
3. That your labeling does not make any medical claims associated with SIDS such as those examples described in this letter.

A written response to us will acknowledge that you have received this letter and have reviewed your labeling for medical claims associated with SIDS. Responses and copies of current and revised labeling can be sent to:

Rebecca Keenan, Consumer Safety Officer
Food and Drug Administration/ Center for Devices and
Radiological Health, OC/DOE2/GHB/HFZ-333
2094 Gaither Road, Rockville, MD 20850

If you choose to market your infant mattresses and/or infant positioners with medical claims, you must submit a Pre-Market Notification [510(k)] application or PMA to FDA within sixty (60) days of receipt of this letter to:

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health, Food and Drug Administration
9200 Corporate Boulevard, Rockville, Maryland 20850 USA

Getting More Information

If you have any questions concerning this letter, please contact: Rebecca Keenan, Consumer Safety Officer, Office of Compliance, Center for Devices and Radiological Health, FDA. Phone: (301) 594-4618; FAX (301) 594-4638; e-mail: rkk@cdrh.fda.gov; Copies of this letter can be found on the following webpage: www.fda.gov/cdrh/SIDS

Sincerely yours,

Lillian J. Gill
Director, Office of Compliance
Center for Devices and
Radiological Health

DEFINITIONS

Medical Device [see section 201(h) of the Food, Drug, and Cosmetic Act (FD&C Act)]- A piece of equipment, apparatus, machine, implant, or other similar article intended for use in the healing, lessening, management or prevention of disease.

Medical Claim- A statement on labeling that declares or implies that the product will heal, lessen, manage, or prevent disease.

Labeling (see CFR Title 21 Part 801) Any written, printed, or graphic material on the direct or outside container of any product as well as any printed materials that accompany the product at the point of sale to a consumer. FDA considers written, printed, or graphic material placed on a manufacturer's or own label distributor's Internet website to be labeling.

Pre-Market Notification [510(k)] (see CFR Title 21 Part 807.81)- An application submitted to the FDA to demonstrate that the medical device to be marketed is substantially the same as a legally marketed device that was or is currently on the United States market.

Pre-Market Approval (see CFR Title 21 Part 814) -An order granting an applicant exclusive approval to market a particular medical device; the required process of scientific review for these devices to establish reasonable assurance of safety and effectiveness

Registration of Medical Device Establishments (see CFR Title 21 Part 807)- All institutions that manufacture, prepare, or initially distribute medical devices are required to register with the Agency as a medical device establishment.

Listing of Medical Devices (see CFR Title 21 Part 807)- All facilities required to register with FDA as a medical device establishment are also required to list their medical devices, including a description of those devices, with the Agency.

Medical Device Reporting (see CFR Title 21 Part 803) - Manufacturers of medical devices, including firms that distribute under their own labels, must report to the FDA any deaths and serious injuries that may have been caused by the device or to which the device may have contributed. Manufacturers must also report certain malfunctions of devices.

Good Manufacturing Practices (see CFR Title 21 Part 820) - Are described in FDA's Quality System Regulations. These regulations require that domestic or foreign manufacturers have a quality system for the design and production of medical devices intended for commercial distribution in the United States.