



June 23, 2014

Notification

PFSB/SD Notification No. 0623-1

To: Commissioner of Prefectural Health Department (Bureau)

Director of Safety Division, Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Self-check of Electric Massage Devices for Home Use

Regarding electric massage devices for home use (including composite medical devices of electric massage device for home use), to advise users to properly use the product as stated by in the precautions of the package insert or the user manual has been requested by PFSB/SD Notification No. 0510-I “Advice on the proper use of electric massage devices for home use (request for cooperation)” that was issued on May 10, 2012.

With recurrent events of strangulation because of clothing getting caught in the roller section, which were caused by incorrect usages of an electric massage device for home use (i.e., use of the product without a cloth cover of the roller section, and use of the product for the back of the user, despite the product being originally intended for the foot), the Marketing Authorization Holder* is urging to stop using its product. In response to the recurrence of these accidents, this notification is issued to ask you to advise the Marketing Authorization Holders of the electric massage devices for home use under your jurisdiction to perform self-check of the products as described below, in addition to giving advices on the proper use of the electric massage devices for home use as previously requested.

Furthermore, this notification asks for your cooperation to provide information widely to the users regarding the proper use of electric massage devices for home use via media, such as prefectural public relations paper.

Moreover, the information is published on the website of the Ministry of Health, Labour and Welfare (<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000048807.html>), and Consumer Affairs Agency and other related organizations are also asked to ensure provision of the information.

1. Target devices

Any manufactured and marketed electric massage devices for home use (including those whose sales has either ended or been suspended) that fall under both the categories below:



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- 1) Portable roller-type massage devices.
- 2) Those with the protection cover (the driving or moving section becomes exposed without the cover) that can be taken off as per the design specification (Washing and/or replacement of the cover is advised by the design concept.)

2. Details of self-check

On the target device, the respective Marketing Authorization Holder should perform self-check as follows:

- 1) Check if the device operates without the protection cover
- 2) If the device can operate under the condition of the item 1), check if a string, clothing, or other object may be caught in the roller of the device without the protection cover.

3. Result of self-check

If the result of self-check suggests that the product may have a risk of a string, clothing, or other object being caught in its roller, consider possible actions taken for the users, such as appropriate information provision, and consult the Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare.

*Matoba Electric Manufacturing Co., Ltd. (The names of the target devices (model): Arubi Shape up Roller (N/A) and Shape up Roller II (SR-5118))