Department of Health, Executive Yuan

Public Announcement

Recipient: As stated in Copies

Document Issue Date: February 2, 2000

Document Issue No.: Wei Shu Yao Tzu No. 89006412

Attachment: See Subject

Subject: Announcing publicly with regard to the change of medical device labeling, instructions, or outer packaging that does not require application approval, as detailed in the attachment, to be implemented from this day forward.

Basis: Article 46 of Pharmaceutical Affairs Act

Announcement: In order to simplify the task of registration amendment of medical devices, "Items for Change of Medical Device Labeling, Instructions, or Outer Packaging that Does Not Require Application Approval" (as in the attachment) are especially stipulated. With effect from this day forward, for those that fulfill the requirements of this announcement, manufacturers may make changes and adjustments to meet market requirements without the need to apply for registration amendment with this Department.

Copies: Keelung City Health Bureau; Department of Health, Taipei City Government; Public Health Bureau of Taipei County; Public Health Bureau of Taoyuan County; Hsinchu City Public Health Bureau; Public Health Bureau of Hsinchu County; Miaoli County Public Health Bureau; Taichung City Health Bureau; Public Health Bureau, Taichung County; Public Health Bureau, Nantou County; Changhua County Public Health Bureau; Public Health Bureau, Yunlin County; Public Health Bureau, Chiayi City; Chiayi County Health Bureau; Tainan City Health Bureau; Tainan County Health Bureau; Department of Health, Kaohsiung City Government; Health Bureau of Kaohsiung County; Pingtung County Health Bureau; Public Health Bureau, Yilan County; Hualien County Health Bureau; Public Health Bureau, Taitung County; Public Health Bureau, Penghu County; Public Health Bureau, Kinmen County; Lienchiang County Health Bureau; Taiwan Medical Industry Association; Taipei Medical Instruments Commercial Association; Taichung Medical Instruments Commercial Association; Kaohsiung Medical Instruments Commercial Association; Taipei Instruments Commercial

Association; Taoyuan County Instruments Commercial Association; Taichung Instruments Commercial Association; Kaohsiung Instruments Commercial Association; Medical Device Division, American Chamber of Commerce in Taipei; German Trade Office Taipei; National Laboratories of Foods and Drugs, Department of Health; Bureau of Pharmaceutical Affairs, Department of Health; Section I, Bureau of Pharmaceutical Affairs, Department of Health; Section II, Bureau of Pharmaceutical Affairs, Department of Health; Central Region Office, Department of Health

[Titles and Signatures Printed]

Minister Chi-Hsien Chan (Abroad)

Vice Minister Chih-Liang Yaung (Acting)

Approved for implementation by the official in charge from a Bureau/Office with authorization according to the provisions of hierarchical responsibility.

Items for Change of Medical Device Labeling, Instructions, or Outer Packaging that Does Not Require Application Approval

1. No Change of Originally Approved Written Contents:
    a. Change in only material, shape, illustration, or color of labeling, instructions, or outer packaging (but does not include change in medical device material, shape, illustration, or color that have prior approval from the Department of Health, and may not include obscene, indecent and effectiveness misguiding illustrations).
    b. Due to change in packaging quantity, proportional shrinkage or expansion of originally approved illustration and text; or change in position of originally approved illustration and text (i.e., change of layout).
    c. Change in font of originally approved written contents (but the font of English product name may not exceed Chinese product name).
    d. Change from stick-on labeling to printing on external box or adding outer packaging (but its text and illustration design should be the same as that of the originally approved labeling).

2. Change of Originally Approved Written Contents
    a. Additional printing or modification: barcode, recycling symbol, medical device GMP certification logo (only allowed for GMP medical devices approved by the Department of Health), CE logo, name or address of distributor, suggested retail price, consumer service hotline, phone, fax, contact address, and company logo, CNS, or registered trademark number approved and registered by the Intellectual Property Office.
    b. Change in name of business applicant, manufacturer name, or manufacturer address (but the amendment of permit license must first be approved by the Department of Health).
    c. Addition, removal, or change of company name that is included in the Chinese and English product name (but the amendment of permit license must first be approved by the Department of Health).