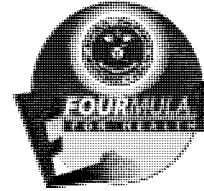


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January 8, 2007

ADMINISTRATIVE ORDER
No. 2007 - 0003

SUBJECT: Policies and Guidelines Governing the Registration and Licensing of Establishments Dealing with Medical Devices

I. RATIONALE

The State is mandated (a) to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and, other social services available to all the people at affordable cost (Section 11, Article 11, Article, 1987 Constitution); (b) to establish and maintain an effective food and drug regulatory system; (c) to undertake appropriate health manpower development and research responsive to the country's health needs and problems (Section 12, Article XIII, 1987 Constitution).

In view thereof, Republic Act No. 3720, as amended by Executive Order No. 175, otherwise known as the "Food, Drugs and Devices and Cosmetic Act" was enacted to establish an effective system in the registration, monitoring, and regulation of food, cosmetics, drugs, devices, and household hazardous substances.

On May 24, 1999, then President Joseph Ejercito Estrada issued Executive Order No. 102, series of 1999 purposely to redirect the functions and operations of the Department of Health, as a result of which the Bureau of Health Devices and Technology (BHDT) was created with regulation of medical and health-related devices as one of its major functions.

Thus, issues concerning the registration of medical devices and licensing of medical device establishments have been raised that have effectively impeded the achievement of the abovementioned constitutional mandate and objectives. It is further realized that there is a necessity to give particular attention to medical devices in the Philippines not only in consonance with the ongoing regional and global harmonization efforts but in relation to the enhancements made by science in medical technology and in line with the efforts being made to rationalize and streamline the operations and capacities of the Department of Health, in general, and the Bureau of Food and Drugs (BFAD) and the BHDT, in

particular, which should result in better health outcomes for Filipinos. In view of the above premises, this order is hereby issued.

II. PURPOSE AND OBJECTIVE

The purpose of this Order is to harmonize the provisions of R.A. No. 3720, as amended, and E.O. No. 102 s. 1999 by establishing policies and guidelines governing the registration and licensing of establishments dealing with medical devices.

In issuing this Order, this Department, through BFAD and BHDT, hereby reiterates and consistently adopts its mandate and responsibility to ensure the safety, efficacy, and good quality of medical devices applied for registration.

III. SCOPE AND COVERAGE

This Order shall cover the registration and licensing of establishments dealing with medical devices defined under R.A. No. 3720, as amended, E.O. 102 s. 1999, and R.A. No. 7394, otherwise known as the “Consumer Act of the Philippines.”

IV. GENERAL GUIDELINES

For the purpose of the effective implementation of this Order, the BHDT shall act as the technical arm of the BFAD on matters relative to the registration and licensing of establishments dealing with medical devices. Accordingly, the following general guidelines shall apply:

1. When filed directly or by way of referral from BFAD, all applications for the registration of medical devices and licensing of their establishments shall be processed, reviewed and evaluated by the BHDT in accordance with prescribed or established guidelines of the Department and/or BFAD.
2. The BHDT, through its Director, shall submit its findings and recommendations to the BFAD Director who in turn shall act on the same.
3. No Certificate of Device Registration or License to Manufacture, Refurbish, Import, Export, Sell, Distribute, Market, and/or Store Medical Devices shall be issued without the approval and signature of the BFAD Director, furnishing a copy thereof to the BHDT.
4. The BHDT Director, being the recommendatory officer, shall be held accountable for all the Certificates of Device Registration or Licenses to be approved by the BFAD Director that have been based on the recommendation of the BHDT Director.
5. Both the BFAD and BHDT shall furnish each other with all necessary information and data as may be needed or required by the other in the spirit of mutual cooperation and support of one another.

6. The Order may be amended or revised from time to time for the effective and efficient implementation of the laws and rules and regulations governing the registration and licensing of establishments dealing with medical devices, unless otherwise changed, modified or rescinded by the Secretary of Health.

V. FEES AND POST-MARKET MONITORING AND SURVEILLANCE

BFAD and BHDT are hereby authorized to charge the appropriate fees in the performance of their respective duties and responsibilities under this Order.

Furthermore, BFAD and BHDT shall jointly formulate and agree on the procedure and manner by each Bureau shall effectively and efficiently conduct the post-market monitoring and surveillance of medical devices.

VI. SEPARABILITY CLAUSE

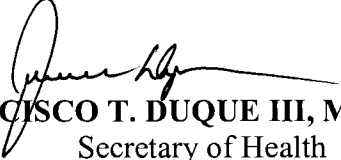
If any part, term or provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected; and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

VII. REPEALING CLAUSE

All other department issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed, and/or revoked accordingly.

VIII. EFFECTIVITY

This Order shall take effect immediately.


FRANCISCO T. DUQUE III, M.D., M.Sc.
Secretary of Health