



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

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23 February 2007

BUREAU CIRCULAR

No. 2007- 004

To : All Concerned

Subject : Guidelines for the implementation of Administrative Order No. 2007 – 0006 (Amendment to Administrative Order No. 46 s. 1988 Re: Organizational Arrangements to Implement the National Drug Policy)

I. Rationale

This circular sets the guidelines for the implementation of Administrative Order No. 2007 – 0006 (Amendment to Administrative Order No. 46 s. 1988 Re: Organizational Arrangements to Implement the National Drug Policy).

The main objective of health regulation under the *FOURmula ONE* for Health is assuring access to quality and affordable health products, devices, facilities and services, especially those commonly used by the poor. To meet this objective one of the strategies identified is to harmonize and streamline systems and processes for licensing, accreditation and certification to make health regulation more rational and client-responsive.

II. Scope of Work and Specific Purpose

For purposes of harmonization and increased transparency and predictability of processed documents, these guidelines shall be implemented in the review and processing of the following applications:

1. New Chemical Entity
2. New Dosage Form/ Strength
3. New Formulation
4. New/Additional Indication
5. Protocol for Monitored Release/ Post-Marketing Surveillance
6. Protocol for Clinical Study (Phase I, II, III)
7. Amendment of Protocol
8. Monitored Release extension
9. Compassionate Special Permit
10. Classification/Reclassification of Products
11. Rationale for Fixed- Dose Combinations
12. Revision/Amendment of Package inserts

13. Importation clearance for Clinical Study
14. Approval for product/ label claim
15. Other applications or documents as may be assigned by the Director, this Office

III. Guidelines

1. All documents for the above applications shall be accepted by the PPAD- PAICS after payment of the fees and charges in accordance with Administrative Order No. 50 s. 2001. These documents shall be forwarded to PSD for initial review prior to referral to the PPAD.
2. Current consultants under the formerly constituted ACB shall be under the PPAD and hence shall, coordinate with the latter, in the review of the documents referred by the PSD.
3. The documents reviewed by the BFAD consultants as well as other appropriate recommendations thereto shall be referred back to PSD, through PPAD, for further review and translation into decision statements before final approval by the Director, this Bureau.
4. PPAD shall release output transactional documents of the aforementioned applications only when such have passed through "completed staff work".
5. All units within BFAD where these applications or any part thereof will be forwarded, shall maintain the necessary records of the subject application or any part thereof, and shall safeguard such records to ensure auditing trail and confidentiality.

IV. Repealing/ Separability Clause

All other BFAD issuances that are inconsistent or contrary to the foregoing are hereby modified and/or modified accordingly.

If any provision of this Circular is declared invalid, the other provisions not affected thereby shall remain valid.

VI. Effectivity

This Circular shall take effect immediately.


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Director IV