Subject: Guidelines for the Monitoring of Milk Code Activities

I. RATIONALE

In the Philippines, the 2003 National Demographic and Health Survey has shown that only 16% of Filipino infants are breastfed exclusively at the age of 4-5 months, leading to undernutrition, which is an underlying cause in 64% of the deaths of children. Malnourished children are less healthy, less intelligent and more vulnerable to infections and illness. Because of this, the Philippines potentially has a tragically and chronically large pool of unhealthy citizens.

The following 2003 data show the gravity of the problems regarding infant and young child feeding in the Philippines:

- 46% of neonates are NOT initiated to breastfeeding within one hour after birth
- 84% of infants are NOT exclusively breastfed at 4-5 months of age
- 50% STOP exclusive breastfeeding at only 3 weeks

One strong explanation for the current health and nutrition situation is that manufacturers and distributors of infant formula and other breastmilk substitutes have taken, over the past twenty (20) years, undue advantage of the loopholes and gaps in the Milk Code to massively penetrate and undermine the breastfeeding in the Philippines. They have conveyed misinformation that undermines breastfeeding while glamorizing infant formula, through false health claims for example, that certain formulations make children geniuses and child prodigies and through the outright peddling of samples in government hospitals and health facilities. Public officials are also manipulated to engage in activities that tend to undermine the importance of breastmilk and breastfeeding through sponsorships, donations and gifts, leading to irreconcilable entanglement and conflicts of interest.
A.O. No. 2006-0012 or The Revised Implementing Rules and Regulations (RIRR) of the Milk Code was promulgated to achieve the relevant constitutional mandates, implement international commitments and provide solutions to the problems identified in scientific and medical studies. The RIRR is not meant to compel women to breastfeed or prohibit or restrict commercial sales of milk substitutes. The RIRR of the Milk Code is meant to ensure that women are provided with accurate and unbiased information to enable them to make an informed choice. This can only be done through regulation of advertisement and promotion of breastmilk substitutes. Particular focus is needed to remove from the medical and public health environment the undue influence brought about by run-away advertisements, sales promotions, donations, sponsorships and other Milk Code activities.

The RIRR seeks to save Filipino children’s lives, now and in the future, by regulating manufacturers and distributors of infant formula and other breastmilk substitutes who, over the past twenty (20) years, have taken undue advantage of the loopholes and gaps in the Milk Code and its previous implementing rules to massively undermine breastfeeding in the Philippines.

II. OBJECTIVE

In coordination with other agencies involved in the implementation of the Milk Code, this Department Circular aims to set forth the guidelines for monitoring the compliance to E.O. No. 51 and A.O. No. 2006-0012 in the national, regional and provincial levels.

III. Composition of the Monitoring Teams – The Monitoring teams shall be composed of the following:

1. National level:
   - National Center for Disease (NCDPC-DOH)
   - National Center for Health Facilities and Development (DCHFD-DOH)
   - Government/Non-government Organizations/Civil Societies without any conflict of interest with the breastfeeding culture, and/or direct or indirect connection, financial or otherwise, or with commercial interest within the scope of the Code.
   - Ad Hoc International Agencies such as the United Nations Children’s Emergency Fund (UNICEF) and the World Health Organization (WHO)

2. Regional/Provincial/City/Municipal/ Barangay levels (in collaboration with their respective Local Government Units):
   - Center for Health Development Offices
   - Provincial Health Offices
   - City Health Offices
   - Municipal Health Offices/Rural Health Units
   - Barangay Health Office
   - DOH-accredited GOs/NGOs/Civil Societies
IV. **Functions of the monitoring Teams**. The monitoring teams shall have the following functions:

1. Monitors compliance as well as problems encountered in the implementation of the Milk Code.
2. Verifies reports of violations of the Milk Code;
3. Monitors labels of products within the scope of the Code and marketing practices in various distribution centers;
4. Recommends sanctions or punitive actions for violations of the Milk Code to the Food and Drug Administration and follow-up action/resolution;
5. Submits regular reports on the status of the Milk Code implementation to the Food and Drug Administration.

V. **Continuing Education of Monitoring Teams**

The DOH shall provide continuing education to the Monitoring Team(s). They may seek technical and financial assistance from donor agencies after exhausting all resources.

VI. **Monitoring Activities**

Official members of the Monitoring team(s) are authorized to carry out monitoring activities at any time, or based on specific reports/suggestions from the Food and Drug Administration in their respective jurisdiction.

In particular, the Monitoring team(s) will be furnished by BFAD with copy/ies of the complete set of information related with all applied events, sponsorships and research, advertisements, and promotional materials so that monitoring activities can be scheduled accordingly.

VII. **Partnership and Networking**:

Official Monitoring teams, are encouraged to engage Civil society organizations, consumer groups, religious groups and other agencies, to closely monitor milk code implementation in their area of jurisdiction, and immediately report to the monitoring team of any alleged violation, found during their activity.

The Department may request for the assistance on non-governmental organizations, civil society, and concerned international agencies in order to better monitor the implementation of these rules.
VII. Reporting

1. Members of the Monitoring teams as well as civil society groups should ensure that any report of alleged violation should be supported by:
   - Date and place where violation was found/seen
   - Specific location (health facility, store, TV ad, Radio/TV Channel)
   - For printed matters, get sample or a picture of the violation
   - For radio/TV AD or programs, clearly specific airing time and TV channel or Radio frequency
   - For website based violations. Provide web link
   - For violative products, e.g. mislabeled or misbranded product, a sample shall be purchased and receipt should be obtained and submitted as part of the evidence
   - In no case shall any member of the Monitoring Team resort to unreasonable searches and seizures of suspected violative products and/or advertising or promotional materials.

2. Civil Society organizations should be encouraged to send report of alleged violation to the respective official teams (National or Regional)

3. Monitoring Teams comprised of duly accredited teams from non-governmental organizations, and/or civil society may report their findings to the Office of the Secretary of Health who shall appropriately respond thereto with sufficient dispatch

VIII. Reporting Forms and Information

National and Regional Monitoring teams will use the Monitoring Report forms (attached as Annex “A”) to report all alleged violations to the respective Field Regulatory Operations Offices for proper action.

The Reporting Forms shall be made available in FDA and DOH Regional Offices, and in the DOH and FDA websites, to wit: www.bfad.gov.ph and www.doh.gov.ph.

IX. Details on how and where to report

Reports may be submitted at the FDA Central Office at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City addressed to the Director or to the CHD Regional Offices addressed to the Regional Director.
In the levels of the City Health Offices, Municipal Health Offices/Rural Health Units, Barangay Health Office, etc., reports may be submitted to the CHD Regional offices in any form/format as long as all the basic information listed in VII.1 are provided.

X. **Feedback on action taken by the Food and Drug Administration (FDA)**

To ensure the smooth and effective conduct of all monitoring activities, the Food and Drug Administration, should provide immediate (within 5 working days) feedback on actions taken based on the received reports of alleged violations.

XI. **Documentation**

National and Regional Monitoring teams, should keep proper documentation of all reported alleged violations.

XII. **Repealing Clause**

All issuances, rules and regulations or parts thereof inconsistent with these guidelines are hereby modified and/or repealed accordingly.

XIII. **Separability Clause**

If for any reason, any part or provision of these guidelines is declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

XIV. **Effectivity**

This guidelines shall take effect immediately.

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health
MONITORING REPORT FORM ON E.O. 51 (MILK CODE)

Date/Time: ____________________________

Mon. No. ______

Place/location:

1) Type of violation: ____________________________

2. Advertising materials
   Type of material: (get sample or picture)
   __ Booklet    __ Leaflet    __ Advertisement    __ Video cassette    __ mail
   __ Audio    __ Compact disk    __ Display    __ Web page    __ text messages
   __ visual    __ Poster    __ Billboard    __ Electronic media    __ telephone calls
   __ Theater    __ Audio-visual    __ Others (specify)

3. Where was the material found/observed?
   __ General Hospital    __ Maternity    __ Pediatric hospital    __ Clinic
   __ Doctor's Office    __ Health centre    __ Pharmacy    __ Supermarket
   __ Shop    __ By the roadside    __ Magazine    __ Radio
   __ Local TV    __ Cable TV    __ Junk mail    __ Cinema
   __ Newspaper    __ Video    __ Scientific journal    __ Others (write here)
   __ Internet

4. Has any company given sponsorship/fellowships/continuing education and other related services or other services? ______ Yes    ______ No

5. Where was the assistance for sponsorship/fellowships/continuing education and other related researches conducted?
   __ national events    materials/activities observed: ____________________________
   __ regional events    Others (specify)
   __ local government events
   __ with certificate of approval
   __ without certificate of approval

6. Who was the recipient of the donation?
   __ orphanage
   __ TV networks
   __ government organizations
   __ non-government organizations
   __ Public officials
   __ Others (specify)

7. What is the type of product donated?
   __ Infant formula,    __ bottle
   __ Follow-on formula    __ teats
   __ Special formula    __ others (specify)
   __ Cereal
   __ Fruit/vegetable/meat puree,
   __ Sweetened condensed milk
8. What is the purpose of the donation? ________________________________

9. Observations made in the hospital/health centers/health facilities?
   ______ presence of medical representatives/visits/decking
   ______ health personnel receiving samples of milk products and gifts
   ______ distribution of companies detailing materials
   ______ product display in the hospital pharmacy
   ______ contact with mothers
   ______ speakers from milk companies during mothers class conference/meetings

   Other materials/activities observed ____________________________
   Described/remarks ________________________________________

10. Has any company sent promoters to the shop to advise consumers on infant feeding or on particular products?
    ______ yes ______ No. If yes, give details: ____________________________________________

11. Is any of the following promotion techniques used to promote sales of infant foods/bottles/teats in this shop? If
    yes, give details in the box below.
    ______ Discounts to customers ______ Product information
    ______ Special displays ______ Special sales
    ______ Coupons ______ Tie-in-sales (buy one, get two, etc.)
    ______ Samples ______ Product launch
    ______ Gifts with purchase ______ Shelf-talkers
    ______ Posters on display ______ Other

12. Does the labels of feeding bottles and teats
    a. carry a photo, drawing or other representation of an infant
       or young child, or a parent feeding a baby? ______ Yes ______ No
       (If YES, please attached photo of offending label)

    b. contain any other drawing, image or text which idealizes the use of the product?
       ______ Yes ______ No
       If YES, describe ________________________________________________

    c. promote breastfeeding substitutes?
       ______ Yes ______ No
       If YES, describe ________________________________________________

    d. have text which suggests similarity of the product to the breast or nipple?
       ______ Yes ______ No
       If YES, describe ________________________________________________

13. Does the label indicate the recommended age of user/s? ______ Yes ______ No
    If YES, what is it? …… Months OR, (other wording) ……………………………

14. Labels of follow-on formula/infant formula
    Does the label:
    a. suggest that a bottle be used for the product? ______ Yes ______ No

    b. carry a photo, drawing or other representation of an infant?
       ______ Yes ______ No
       (If YES, please attach photo of offending label)

    c. resemble the company’s infant formula labels? ______ Yes ______ No

    e. indicate or suggest in any way that this product could be for babies under six months?
       ______ Yes ______ No
Details and comments:

Remarks/Findings/Proposed Action/Action
Taken:

Monitored by:

(Signature over Printed Name)

Designation