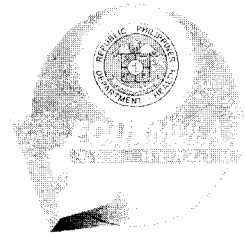


Republic of the Philippines
Department of Health

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15 May 2006

ADMINISTRATIVE ORDER

No. 2006 - 0012

SUBJECT: Revised Implementing Rules And Regulations of Executive Order No. 51, Otherwise Known as The “Milk Code”, Relevant International Agreements, Penalizing Violations Thereof, and for Other Purposes

WHEREAS, Section 15 Article II of the 1987 Constitution of the Philippines states that “The State shall protect and promote the right to health of the people and instill health consciousness among them”;

WHEREAS, Section 2, Article II of the 1987 Constitution of the Philippines states in part that “The Philippines x x x adopts the generally accepted principles of international law as part of the law of the land x x x”.

WHEREAS, the Philippines has adopted the WHO and UNICEF “2002 Global Strategy on Infant and Young Child Feeding”, and the various World Health Assembly Resolutions to implement the same, and therefore is legally and morally obligated to follow their provisions.

WHEREAS, towards this end, the State shall support the “2002 Global Strategy on Infant and Young Child Feeding” and exerts efforts to address the provision of safe and adequate nutrition for infants and young children, by the protection, promotion and support of breastfeeding;

WHEREAS, the WHO/UNICEF Global Strategy on Infant and Young Child Feeding recommends not only exclusive breast milk for newborns, but also indigenous, fresh and natural foods in combination with continued breastfeeding for infants and young children. It is guided by the World Health Assembly Resolutions, Codex Alimentarius, and consistent with national laws or national policies;

WHEREAS, adequate and proper nutrition is an important and universally recognized component of each child’s right to the enjoyment of the highest attainable standard of health as provided for in the United Nations Convention on the Rights of the Child, which the Philippine Senate, in accordance with its constitutional prerogative under Section 21, Article VII, of the 1987 Constitution, ratified on July 26, 1990, and which mandates the Philippines to implement various international agreements relevant to Infant and Young Child Feeding;

WHEREAS, the use of breastmilk, which is widely recognized as the best source of nutrition for babies, promotes the development of emotional bonding between the mother and child, bestows upon the newborn infant protection against infection, provides for the mother natural contraception after delivery, and protects the mothers from closely spaced pregnancy.

WHEREAS, with the resultant healthier population and the reduction in infant and under five mortality rates, the country will be closer in reaching its targets for the Millennium Development Goals;

WHEREAS, breastfeeding is the most far-reaching and the least costly strategy for the alleviation of poverty.

NOW THEREFORE, Pursuant to the authority under Section 12(b)(1) of Executive Order No. 51 dated 20 October 1986, otherwise known as “National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products,” the Department of Health, through the Honorable Secretary of Health, hereby promulgate the ensuing revised rules and implementing regulations:

RULE I

ENABLING PROVISIONS

SECTION 1. Title. – The following shall be referred to as the “Revised Implementing Rules and Regulations of Executive Order No. 51, otherwise known as the ‘Milk Code’, Relevant International Agreements, Penalizing Violations Thereof, And For Other Purposes”.

SECTION 2. Purpose. - These Revised Rules and Regulations are hereby promulgated to ensure the provision of safe and adequate nutrition for infants and young children by the promotion, protection and support of breastfeeding and by ensuring the proper use of breastmilk substitutes, breastmilk supplements and related products when these are medically indicated and only when necessary, on the basis of adequate information and through appropriate marketing and distribution.

SECTION 3. Scope and Coverage. – These Revised Rules and Regulations shall apply to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

SECTION 4. Declaration of Principles. – The following are the underlying principles from which the revised rules and regulations are premised upon:

- a. Exclusive breastfeeding is for infants from 0 to six (6) months.
- b. There is no substitute nor replacement for breastmilk.
- c. Appropriate and safe complementary feeding should start from six months onwards in addition to breastfeeding.
- d. Breastfeeding is still appropriate for young children up to two (24 months) years of age or beyond.
- e. Infant or milk formula may be hazardous to a child's health and damage child's formative development.
- f. Advertising, promotions, or sponsorships of infant formula, breastmilk substitutes and other related products are prohibited.
- g. Other related products such as, but not exclusive of, teats, feeding bottles, and artificial feeding paraphernalia are prohibited in health facilities.
- h. Government and all concerned stakeholders must continuously accomplish an information, dissemination campaign/strategy, and do further research on the advantages of breastmilk and the hazards of breastmilk substitutes or replacements.
- i. Milk companies, and their representatives, should not form part of any policymaking body or entity in relation to the advancement of breastfeeding.

RULE II

DEFINITION OF TERMS

SECTION 5. Definition of Terms. - For purposes of these Revised Rules and Regulations, the term:

(a) "Advertising" refers to any representation by any means whatsoever for the purpose of promoting the sale or distribution of breastmilk substitutes/supplements and other related products under the scope of this Code;

(b) "BFAD" refers to the Bureau of Food and Drugs of the Department of Health;

- (c) “**Breastmilk substitute**” means any food being marketed or otherwise represented as partial or total replacement of breastmilk whether or not suitable for that purpose;
- (d) “**Committee**” shall refer to the Inter-Agency Committee created under E.O. No. 51, s. 1986 composed of the Secretary of Health, as Chairman, and the Secretary of Trade and Industry, the Secretary of Justice, and the Secretary of Social Welfare and Development, as members;
- (e) “**Complementary**” means any food, except milk substitutes, whether manufactured or locally prepared, suitable as a complement to breastmilk to satisfy the nutritional requirements of the infant;
- (f) “**Container**” means any form of packaging of products for sale as a normal retail unit, including wrappers;
- (g) “**Distributor**” means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code;
- (h) “**DoH**” refers to the Department of Health;
- (i) “**Exclusive breastfeeding**” means giving only breastmilk without water, liquids, teas, herbal preparations, or other food and fluid intake for the first six months of life;
- (j) “**Gifts of any sort**” means any form of financial, personal or commercial reward, inducement, incentives and other favors provided directly or indirectly by manufacturers, distributors, and their representatives, of products within the scope of the Code;
- (k) “**Health care system**” means governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child care institutions;
- (l) “**Health Facilities**” means health care systems including but not limited to health centers, clinics, birthing and parenting classes venues, hospitals, maternal centers/clinics, birthing homes, barangay health stations, health and nutrition posts and lying in clinics;
- (m) “**Health Worker**” means a person working in a component of such health care system, whether professional or non-professional, including volunteer workers. It also includes health workers in private practice. Traditional and other birth attendants, their assistants and other community volunteers involved in health and nutrition promotion and education shall likewise be covered;
- (n) “**Infant**” shall refer to a person within the age bracket of 0 -12 months;
- (o) “**Infant Formula**” means one of the breastmilk substitutes formulated industrially in accordance with applicable Codex Alimentarius standards;

- (p) **“Label”** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of any product within the scope of this Code;
- (q) **“Latching on”** means that with the assistance of the health worker and immediately after its delivery, the infant is placed to the breast of the mother in order to initiate suckling;
- (r) **“Manufacturer”** means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code;
- (s) **“Marketing firm”** refers to an entity that does marketing or provides marketing services;
- (t) **“Marketing Materials”** and/or **“services”** means the promotion, distribution, selling, advertising, public relations, information services, internet promotion and communication and information dissemination, in whatever form, including but not necessarily limited to, mail, email, text messages, telephone calls, website advertising, television, motion pictures, stage plays and radio programs, whether live or taped;
- (u) **“Marketing personnel”** means any person whose functions involve the marketing of a product or products within the scope of this Code;
- (v) **“Medically Indicated”** means special milk formula indicated for infants with inborn errors of metabolism, i.e. galactosemia, phenylketonuria* and maple syrup urine disease;
- (w) **“Milk company”** shall refer to the owner, manufacturer, distributor, of infant formula, follow-up milk, milk formula, milk supplement, breastmilk substitute or replacement, or by any other description of such nature, including their representatives who promote or otherwise advance their commercial interests in marketing those products;
- (x) **“Natural and indigenous food”** means locally grown or produced foods which are neither artificial nor processed;
- (y) **“Other milk products, foods and beverages”** refers to any provision or drink marketed as a partial or total replacement of breastmilk;
- (z) **“Other related products”** refers to all materials used to administer breastmilk substitutes; such as, but not limited to, feeding bottles, teats and other artificial feeding paraphernalia;



- (aa) “**Products within the scope of this Code**” shall pertain to breastmilk substitutes and infant formula, including bottle-fed complementary foods, as well as teats and other commodities which intend to replace or substitute, in whole or in part, breastmilk and breastfeeding;
- (bb) “**Promotions**” means employing any method, scheme, or design, of directly or indirectly, encouraging or enticing people, or group of persons, in whatever form, whether by chance or skill, to purchase or acquire products within the scope of the Code;
- (cc) “**Sample**” refers to single or small quantities of a product provided for free;
- (dd) “**Sponsorships**” shall refer to milk companies, and their agents/representatives, hosting, initiating, or otherwise providing games, sport or cultural events, charities, dances/balls, conventions, meetings, youth and women seminars or classes, and other like activities, for the purpose of promoting, directly or indirectly, their products covered within the scope of this Code;
- (ee) “**Supplies**” refers to quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.
- (ff) “**Young Child**” means a person from the age of more than twelve (12) months up to the age of three (3) years (36 months).

RULE III

INFORMATION AND EDUCATION

SECTION 6. *Responsibility.* - The Department of Health shall take measures to promote, protect, support and monitor appropriate infant and young child feeding (IYCF) practices. Appropriate IYCF practices include the following:

- Proper Latching-on immediately after birth and initiation of breastfeeding within the first thirty (30) minutes thereafter
- exclusive breastfeeding from 0 - 6 months
- appropriate complementary feeding from 6 months onwards
- continuous breastfeeding up to two (2) years of age or beyond

The goals will be achieved by providing women access to the support that they require – in the family, the community, and the workplace. DOH shall provide objective, updated and consistent information and training of health workers and the general public on infant and young child nutrition in partnership with the local governments and civil societies without any conflict of interest.

SECTION 7. – *Hazards and Complete Information on Breastmilk*



Substitutes and Replacements. - It is the responsibility of the State to inform the general public on the hazards of the production, preparation and use of breastmilk substitutes and other products covered by the Code. When medically indicated and only when necessary, the use of breastmilk substitutes is proper if based on complete and updated information.

SECTION 8. Information and Education. - The government shall ensure that objective and consistent information is provided on infant and young child feeding, for use by families and those involved in the field of infant nutrition. This responsibility shall cover the planning, provision, design and dissemination of information, and the control thereof.

- a) In this regard, The Department of Health in collaboration with the national agencies, local government units, including non - governmental organizations and members of civil society, shall :
 - a.1. Plan, provide, design, disseminate and regulate information related to infant and young child nutrition and the implementation of the Milk Code;
 - a.2. Formulate and implement a communication plan, which among others will indicate key messages on infant and young child nutrition;
 - a.3. Create a Technical Working Group to serve as a clearing house for all information and training materials on infant and young child nutrition and the Milk Code; and
 - a.4. Assist Local Government Units (LGU's) and other partners in developing strategies to promote breastfeeding and infant and young child nutrition.
- b) Informational and educational materials intended to reach pregnant women and mothers of infants, including women of reproductive age, which materials shall include clear information on all of the ensuing; (1) the benefits and superiority of breastfeeding; (2) maternal nutrition, and the preparation for and maintenance of breastfeeding; (3) the negative effect on breastfeeding of introducing partial bottle-feeding; (4) the difficulty of reversing the decision not to breastfeed; and (5) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and in particular, the health hazards of unnecessary or improper use of infant formula and other related products including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.
- c) The promotion, protection and support of breastfeeding and the proper implementation of the Milk Code shall be an integral part of all

information, education, and communication plans and training activities of the Department of Health (DoH), as well as that of the Department of Education (DEPED), Department of Social Welfare and Development (DSWD), Local Government Units (LGU's), and other such concerned agencies/individuals.

RULE IV

RESEARCH

SECTION 9. *Research, Ethics Committee, Purpose.* - The DOH shall ensure that research conducted for public policy purposes, relating to infant and young child feeding should, at all times, be free from any commercial influence/bias; accordingly, the health worker or researcher involved in such must disclose any actual or potential conflict of interest with the company/person funding the research. In any event, such research and its findings shall be subjected to independent peer review. Towards accomplishing these ends;

- a. Assistance for research and clinical trials given by manufacturers and distributors are allowed only upon approval by an ethics committee led by DOH. The same committee shall monitor said researches.
- b. The researches shall be conducted in accordance with an approved protocol. Any changes in the protocol after it has been approved will be subject to a new review and approval by the Ethics Committee.
- c. Assistance for research maybe allowed subject to the following conditions:
 - c.1. Researches involving well or ill infants and children as subjects shall be limited to physiological factors and therapeutic studies;
 - c.2. These studies should in no case be harmful to the subject; and
 - c.3. Should be limited to those with potential benefits for the particular subject.
- d. Recipients of research awards shall not allow themselves, their organizations or their subjects, to be used directly or indirectly for any promotional activity related to products within the scope of the Code. These may be by way of display of posters and streamers patronizing the Company, their products, and/or as lecturers/speakers or testimonials in the promotion of the products that undermine breastfeeding.



- e. Assistance for support of laboratory costs, reagents and other materials shall be allowed only upon approval and review by the Ethics Committee regarding their use based on a submitted protocol.

SECTION 10. Public Disclosure. - For transparency purposes, a disclosure and/or disclaimer of the sponsoring company should be done by the company itself, health worker, researcher involved through verbal declaration during the public presentation of the research and in print upon publication.

RULE V

ADVERTISING, PROMOTION, MARKETING And SPONSORSHIPS

SECTION 11. Prohibition. - No advertising, promotions, sponsorships, or marketing materials and activities for breastmilk substitutes intended for infants and young children up to twenty-four (24) months, shall be allowed, because they tend to convey or give subliminal messages or impressions that undermine breastmilk and breastfeeding or otherwise exaggerate breastmilk substitutes and/or replacements, as well as related products covered within the scope of this Code.

Section 12. Authority of the Inter-Agency Committee (IAC). - The Inter Agency Committee (IAC) shall review all advertising, promotion or other marketing materials, whether written, audio, visual, cinema, theater, audio-visual and electronics, including but not limited to mail, email, text messages, telephone calls and website advertising, and for communication and information dissemination in any form, for products within the scope of this Code.

The Committee shall develop/update substantive and procedural guidelines for reviewing advertising, promotional and marketing materials, including its screening when deemed appropriate. All such materials must have been approved and consented to in writing by the Committee before the Company's first public or commercial exhibition.

All approved advertisement and/or promotional materials for milk supplements, complementary food, feeding bottles & teats and related products must bear the messages both in English and in Filipino.

The DOH based on the latest scientific information and products may modify the messages, provided that wide dissemination of the message to all concerned is ensured.

SECTION 13. "Total Effect". - Promotion of products within the scope of this Code must be objective and should not equate or make the product appear to be as good or equal to breastmilk or breastfeeding in the advertising concept. It must not in any case undermine breastmilk or breastfeeding. The "total effect" should not directly or indirectly

suggest that buying their product would produce better individuals, or resulting in greater love, intelligence, ability, harmony or in any manner bring better health to the baby or other such exaggerated and unsubstantiated claim.

SECTION 14. *Prior Written Consent and Approval of Committee.* – No advertising, promotion or other marketing materials whether written, audio, visual, audio-visual, and electronic for products within the scope of this Code, which are marketed as partial or total replacement of breastmilk, including bottle-fed complementary foods shall be printed, published, distributed, exhibited, and broadcasted or in any manner released to the public without the prior written consent and approval of the Committee.

No blanket or general approval shall be allowed. Such written approval must be specific in product and time bound.

SECTION 15. *Content of Materials.* - The following shall not be included in advertising, promotional and marketing materials:

- a. Texts, pictures, illustrations or information which discourage or tend to undermine the benefits or superiority of breastfeeding or which idealize the use of breastmilk substitutes and milk supplements. In this connection, no pictures of babies and children together with their mothers, fathers, siblings, grandparents, other relatives or caregivers (or *yayas*) shall be used in any advertisements for infant formula and breastmilk supplements;
- b. The term “humanized”, “maternalized”, “close to mother’s milk” or similar words in describing breastmilk substitutes or milk supplements;
- c. Pictures or texts that idealize the use of infant and milk formula.

RULE VI

PROHIBITED ACTS

SECTION 16. All health and nutrition claims for products within the scope of the Code are absolutely prohibited. For this purpose, any phrase or words that connote to increase emotional, intellectual abilities of the infant and young child and other like phrases shall not be allowed.

SECTION 17. False or misleading information or claims of products within the scope of the Code are prohibited.

SECTION 18. No financial or material inducements or gifts of any sort to promote products within the scope of this Code shall be offered or given by milk companies nor

accepted by health workers and/or members of their families.

SECTION 19. Manufacturers, distributors and marketing firms or their representatives of products within the scope of this Code are prohibited from donating or giving directly or indirectly, samples and supplies to any member of the general public, to hospitals, and other health facilities, including their personnel and members of their families.

SECTION 20. Manufacturers, distributors and marketing firms or their representatives of products within the scope of this Code are prohibited from using the health workers and the health care system in the dissemination, distribution and promotion of products within the scope of the Code.

SECTION 21. Gifts of any sort from milk companies/manufacturers, distributors, and representatives of products within the scope of this Code, with or without company name or logo or product or brand name shall not be given to any member of the general public, to hospitals and other health facilities, including their personnel and members of their families.

SECTION 22. No manufacturer, distributor or representatives of products covered by the Code shall be allowed to conduct or be involved in any activity on breastfeeding promotion, education and production of Information, Education, and Communication (IEC) materials on breastfeeding, holding of or participating as speakers in classes or seminars for women and children activities and to avoid the use of these venues to market their brands or company names.

SECTION 23. There shall be no point of sale advertising, giving of samples or any promotion devices to induce sales directly to the consumers at the retail level, such as special displays, discount coupons, premiums, rebates, special sales, bonus and tie-in sales, loss-leaders, prices or gifts for the products within the scope of this Code.

SECTION 24. Neither the container nor the label of milk products within the scope of this Code shall have pictures of babies and children together with their mothers, fathers, siblings, grandparents, other relatives or caregivers (or *yayas*) or such other pictures and graphics of similar import.

RULE VII

CONTAINERS/LABELS

SECTION 25. *Appropriate Use.* - Containers and labels shall be designed to provide the necessary information about the appropriate use of the products within the scope the Code and in such a way as not to undermine, or equate it to, breastfeeding.



SECTION 26. Content. - Each container/label shall contain such message, in both Filipino and English languages, and which message cannot be readily separated therefrom, relative the following points:

- a) *The words or phrase "Important Notice" or "Government Warning" or their equivalent;*
- b) *A statement of the superiority of breastfeeding;*
- c) *A statement that there is no substitute for breastmilk;*
- d) *A statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use;*
- e) *Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation, and*
- f) *The health hazards of (the use) unnecessary or improper use of infant formula and other related products including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.*

SECTION 27. Infant Feeding Warning. - Food products within the scope of this Code marketed for infant feeding, which do not meet all the requirements of an infant formula but which can be modified to do so, shall carry on the label, a warning that the unmodified product should not be the sole source of nourishment of an infant.

SECTION 28. BFAD's Authority. - The labels of food products within the scope of this Code shall, in addition to the requirements in the preceding paragraphs, conform to the rules and regulations of the BFAD.

RULE VIII

QUALITY AND STANDARD

SECTION 29. Quality. - The quality of products is an essential element for the protection of the health of infants and young children and therefore shall be of highly recognized standard.

SECTION 30. Standards. - Food products within the scope of this Code shall, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

SECTION 31. Against Adulteration and the Like. - To prevent quality deterioration, adulteration or contamination of food products within the scope of this

Code, distribution outlets, shall not be allowed to open cans and boxes for the purpose of retailing them by the cup, bag or in any other form.

RULE IX

HEALTH WORKERS And The HEALTH CARE SYSTEM

SECTION 32. *Primary Responsibility of Health Workers.* - It is the primary responsibility of the health workers to promote, protect and support breastfeeding and appropriate infant and young child feeding. Part of this responsibility is to continuously update their knowledge and skills on breastfeeding. No assistance, support, logistics or training from milk companies shall be permitted.

SECTION 33. *Role of Academe and Others.* - The academe and allied health institutions shall ensure basic education and training on Infant and Young Child Feeding (ICYF) and lactation management.

SECTION 34. *Classes, Seminars For Women.* - In order to protect women of reproductive age, including pregnant mothers, milk companies and their representatives, shall not be allowed to hold any activity in the guise of classes, seminars, recreation activities, fora, and the like, regardless whether or not such activities are intended to promote the products covered by the Code.

SECTION 35. *No Promotions.* - The health workers and the health care system shall not be used for dissemination, distribution and promotion of products within the scope of this Code. No health care facility should be used for promotions of products within the scope of this Code nor as venues that undermine breastfeeding.

RULE X

MONITORING And IMPLEMENTATION

SECTION 36. *Monitoring, Implementation, Functions.* - The Department of Health shall be primarily responsible for the monitoring, implementation and enforcement of the Milk Code and these Implementing Rules and Regulations.

In coordination with other agencies involved in the implementation of the Code, the Department shall adopt such appropriate monitoring guidelines for the national, regional and provincial levels. It shall likewise provide regular training on monitoring compliance and enforcement on violations of the Milk Code for all persons engaged in or volunteering to help in the monitor and implementation of the Code. The Department may request for the assistance of non – governmental organizations, civil society, and concerned international

agencies in order to better monitor the implementation of these rules.

Accordingly, a monitoring team, composed of the ensuing, is hereby created and established :

National level:

- National Center for Disease Prevention and Control (NCDPC)
- National Center for Health Facilities and Development (NCHFD)
- 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/or the World Health Organization (WHO)

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
- GOs/NGOs/Civil Societies

The **Monitoring Team** shall have the following functions:

- Monitors compliance as well as problems encountered in the implementation of the Milk Code.
- Reviews/acts on reports of violations of the provisions of the Code.
- Verifies reports of violations of the Milk Code.
- Monitors labels of products within the scope of the Code and marketing practices in various distribution centers.
- Recommends sanctions or punitive actions for violations of the Milk Code to the Bureau of Food and Drugs.
- Submits regular reports on the status of the Milk Code implementation to the Bureau of Food and Drugs.

SECTION 37. Report to the Secretary of Health. - 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.

SECTION 38. Role of DoH/BFAD in IAC. – The Department of Health shall convene and chair the Inter - Agency Committee (IAC) with BFAD acting as its

RULE XI

FILING Of ADMINISTRATIVE And CRIMINAL COMPLAINT

SECTION 39. Role of Bureau of Food and Drugs (BFAD). – The Bureau of Food and Drugs (BFAD) shall investigate and verify reports of violations; when appropriate, apply administrative sanctions against the violators; and/or file criminal complaints against persons and entities found to have violated, singly or repeatedly, the provisions of the Code or these implementing rules and regulations.

SECTION 40. National Level Violations.- Reports of violations of the Milk Code committed at the national level shall be filed and investigated at the Bureau of Food and Drugs.

SECTION 41. Regional/Provincial Level Violations. - Problems/violations arising at the regional/provincial levels shall be filed, investigated and resolved at these levels. The regional/provincial level shall notify BFAD of any action taken relative to the aforesaid problems/violations. Violations that require prosecution or imposition of administrative sanction as stated in these rules shall be elevated to the BFAD for appropriate action.

SECTION 42. Meaning of National/Regional/Provincial Level Violations. – When the violation consists of commercial exhibition or advertisement for those products within the scope of this Code and found in areas beyond regions, then the violation is deemed to be national. When found or existing in a specific region only, then regional and so on down to the other geographical areas.

SECTION 43. Issuance of Cease and Desist Orders (CDO's). – Immediately upon receipt of the report of violation, the investigating officer shall conduct an *ex parte* examination of the evidence presented. If a prima facie case is established, a Cease and Desist Order (CDO) shall be issued by the BFAD Director or the DoH Regional Director, as the case may be.

Non-compliance with the CDO shall be ground for the imposition of administrative sanctions as stated in Section 47 (f) hereof. The issuance of the CDO shall be without prejudice to the imposition of the appropriate administrative sanction, if so warranted, after due notice and hearing.

SECTION 44. Authority of the IAC To Issue CDO. The IAC Secretariat shall have the authority to determine if any advertising, marketing, or promotional material violates these Rules and Regulations. In such case, the IAC Secretariat shall issue a CDO, signed by the IAC Chairperson stopping the further release, printing, broadcast,

or dissemination of the violative advertising, marketing, or promotional material.

In instances where the CDO is not complied with, the rules stated in the second paragraph of the preceding section shall apply.

SECTION 45. *Role of the Department of Justice.* – The Department of Justice (DoJ) shall cause the criminal prosecution of the violators of this Code.

RULE XII

ADMINISTRATIVE SANCTIONS

SECTION 46. *Administrative Sanctions.* – The following administrative sanctions shall be imposed upon any person, juridical or natural, found to have violated the provisions of the Code and its Implementing Rules and Regulations:

- a) 1st violation – Warning;
- b) 2nd violation - Administrative fine of a minimum of Ten Thousand (P10,000.00) to Fifty Thousand (P50,000.00) Pesos depending on the gravity and extent of the violation, including the recall of the offending product;
- c) 3rd violation – Administrative Fine of a minimum of Sixty Thousand (P60,000.00) to One Hundred Fifty Thousand (P150,000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, and suspension of the Certificate of Product Registration (CPR);
- d) 4th violation – Administrative Fine of a minimum of Two Hundred Thousand (P200,000.00) to Five Hundred (P500,000.00) Thousand Pesos, depending on the gravity and extent of the violation; and in addition thereto, the recall of the product, revocation of the CPR, suspension of the License to Operate (LTO) for one year;
- e) 5th and succeeding repeated violations - Administrative fine of One Million (P 1,000,000.00) Pesos, the recall of the offending product, cancellation of the CPR, revocation of the License to Operate (LTO) of the company concerned, including the blacklisting of the company to be furnished the Department of Budget and Management (DBM) and the Department of Trade and Industry (DTI);

- f) An additional penalty of Two Thousand Five Hundred (P2,500.00) Pesos per day shall be made for every day the violation continues after having received the order from the IAC or other such appropriate body, notifying and penalizing the company for the infraction.

For purposes of determining whether or not there is "repeated" violation, each product violation belonging or owned by a company, including those of their subsidiaries, are deemed to be violations of the concerned milk company and shall not be based on the specific violating product alone.

SECTION 47. Fees, Charges and Fines. – All fees collected, charges imposed and administrative fines that have accrued as a consequence of the implementation of these Rules shall be for the account and income of the Bureau of Food and Drugs.

SECTION 48. Against Public Employees.- In accordance with the Administrative Code and pertinent Civil Service rules and regulations, erring government employees found to be liable, and depending on the gravity of said violation, shall be imposed the appropriate penalty by the disciplining authority.

SECTION 49. Liability of Manufacturers/Distributors. - Manufacturers and Distributors of the products covered by the Code shall be directly liable for any violation of the provisions of the Code and its IRR. Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore, shall be made accountable.

Agents/Representatives of the Manufacturers or Distributors of the products within the scope of the Code, who commit any violation of the provisions of the Code and its implementing rules and regulations shall be jointly and solidarily liable with the said manufacturers and distributors.

RULE XIII

CRIMINAL PENALTIES

SECTION 50. Penalties. - Any person who violates the provisions of this Code or these rules and regulations shall, upon conviction, be punished by a penalty of two (2) months to one (1) year imprisonment or a fine of not less than One Thousand Pesos (P1,000.00) nor more than Thirty Thousand Pesos (P30,000.00) or both. Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore, shall be penalized.

RULE XIV

MISCELLANEOUS PROVISIONS

Section 51. *Donations Within the Scope of This Code.* - Donations of products, materials, defined and covered under the Milk Code and these implementing rules and regulations, shall be strictly prohibited.

Section 52. *Other Donations By Milk Companies Not Covered by this Code.* - Donations of products, equipments, and the like, not otherwise falling within the scope of this Code or these Rules, given by milk companies and their agents, representatives, whether in kind or in cash, may only be coursed through the Inter Agency Committee (IAC), which shall determine whether such donation be accepted or otherwise.

SECTION 53. *Construction.* - All doubts in the implementation and interpretation of the provisions of these implementing rules and regulations shall be resolved in favor of and for the promotion of breastfeeding and against breastmilk substitutes and replacements.

SECTION 54. *Supplemental Administrative Issuances.* - The Secretary of Health, or his duly authorized representative, may issue such additional implementing rules and regulations as may be necessary to further clarify any part of this IRR.

SECTION 55. *Continuous Review on Prescription Policy.* - The Department of Health shall evaluate every year, or as necessary, its policy of whether or not to subject the sale of infant formula or breastmilk substitutes, to prescription.

SECTION 56. *Extending Prohibition For Brandnames and Company Logo Identification.* - The Department shall periodically review whether or not to allow or prohibit the use of brandnames or company logos of products within the scope of this Code which are similar to the brandnames or logos utilized for products not covered by this Code, including the physical appearance of the container, taking into consideration the possibility of product confusion, the balance between a free market economy as against the decline and fall of breastfeeding rates among mothers and women of reproductive age, and public welfare and benefit being its ultimate yardstick. Accordingly, any modification of existing policy should first undergo public consultations with all concerned stakeholders before its actual implementation.

RULE XV

FINAL PROVISIONS


SECTION 57. Repealing Clause. – All orders, issuances, and rules and regulations or parts thereof inconsistent with these revised rules and implementing regulations are hereby repealed and modified accordingly.

SECTION 58. Separability Clause. – If for any reason, any part or provision of these Revised Rules and Implementing Regulations, be declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

SECTION 59. Effectivity. – These Revised Rules and Regulations shall take effect fifteen (15) days after its publication in a newspaper of general circulation with the requisite copy submitted to the University of the Philippines Law Center.

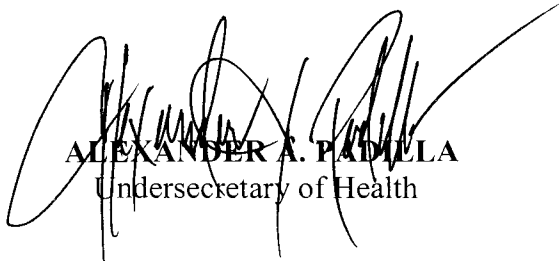
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Approved by the National Executive Committee of the Department of Health in its Regular Meeting of 15 May 2006, at the Office of the Secretary, San Lazaro Compound, Rizal Avenue, Sta. Cruz, City of Manila



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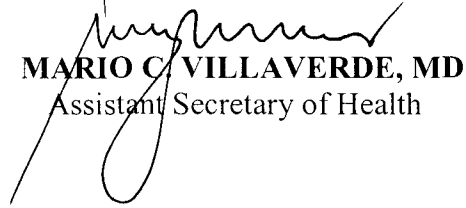

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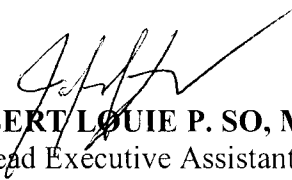


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