



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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ADMINISTRATIVE ORDER

NO. _____

SUBJECT: Ethical Standards for Health Product Promotion

I. BACKGROUND AND RATIONALE

In accord with the 1987 Constitution, it is the State's policy to protect and promote the right to health of the people and instill health consciousness among them (Sec. 15, Art. II). This includes the adoption of 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 (Sec. 11, Art. XIII), as well as the establishment and maintenance of an effective food and drug regulatory system (Sec. 12, Art. XIII), among others.

The Food, Drug, and Cosmetic Act (R.A. No. 3720) also provides that it is State policy to insure safe and good quality supply of food, drugs, and cosmetics, and to regulate the production, sale, and traffic of the same to protect the health of the people (Sec. 2, Chapter II).

In order to successfully provide effective, safe and good quality drugs, as well as to protect the people's rights to health, it is essential to maintain professionalism and high ethical standards in the interactions among the stakeholders in the pharmaceutical industry, including manufacturers, distributors, traders, healthcare **professionals**, healthcare-related institutions and patients organizations. Towards this end, Section 4 (o) of R.A. No. 3720, as (amended by RA 9711) mandated the Food and Drug Administration (FDA) under the Office of the Secretary, Department of Health (DOH), to prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about health products. Related thereto, Republic Act No. 7394 or The Consumer Act of the Philippines also provides that the State through the DOH, shall protect the consumer from misleading advertisements and fraudulent sales promotion practices, (Arts. 108 and 109, Chapter VI, R.A.7394)

Over the years, most cases filed with the FDA regarding consumer complaints dealt with product advertisements with deceptive/misleading or unapproved claims, promotion of ethical products, etc. for which FDA issued Cease and Desist Orders and imposed penalties. There were also cases of repeated violations despite warnings from FDA with eventual cancellation of CPRs, non-issuance of LTOs, etc.

The Philippines as a member of the Asia-Pacific Economic Cooperation (APEC) supports APEC's thrust to promote the growth of small and medium enterprise (SME) which has been hampered by inappropriate business practices. These unethical business practices,

1 especially in the area of product promotion imposed a significant market access barrier and
2 high costs for SMEs in the health products sector.

3
4 To address these problems of unethical and inappropriate business practices which
5 have been identified as an impediment to economic growth, APEC has endorsed certain
6 principles for codes of business ethics for players in the medical device and
7 biopharmaceutical sectors, among others. These principles are specifically contained in two
8 documents, namely (a) The Kuala Lumpur Principles: Medical Device Sector Codes of
9 Ethics; and (b) The Mexico City Principles for Voluntary Codes of Business Ethics in the
10 Biopharmaceutical Sector. The Philippine government has signed both documents and the
11 FDA has also issued Circular No. 2013-024 and Circular No. 2014-007, adopting both Codes
12 for local application.

13 14 **II. OBJECTIVE**

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16 Considering the above premises and pursuant to Section 4(o) of R.A. 3720 as
17 amended-by R.A. 9711, this Order seeks to consolidate and clarify existing regulations and
18 guidelines on marketing and promotion of pharmaceutical and medical devices products and
19 to prescribe new ethical standards for marketing, promotion, and advertisement of health
20 products pursuant to the Mexico City and Kuala Lumpur Principles.

21 22 **III. SCOPE AND COVERAGE**

23
24 This Order pertains to the advertisement, promotion and other marketing activities for
25 pharmaceutical products, including over-the-counter (OTC) drugs and **medical devices** in the
26 Philippines.

27
28 It shall apply to all natural and juridical persons and entities engaged in the marketing
29 and promotion of said products and/or their industry association. It shall apply to health care
30 professionals, health-related institutions and patient organizations insofar as their interactions
31 with persons that market and promote these products are concerned.

32 33 **IV. DEFINITION OF TERMS**

34
35 For the purposes of this Circular, the following definition of terms shall govern:

- 36
37 a. “Advertisement”- means the prepared and through any form of mass medium,
38 subsequently applied, disseminated or circulated advertising matter. (RA 7394). It
39 shall also include any representation by any means for the purpose of promoting
40 directly or indirectly the sale of disposal of any pharmaceutical product. (AO 65 s
41 1989).
- 42 b. “Advertising Agency or Agent” – means a service organization or enterprise creating,
43 conducting, producing, implementing or giving counsel on promotional campaigns or
44 program through any medium for and in behalf of any advertiser.
- 45 c. “Company”- means a duly registered organization that develops, manufactures, sells
46 markets or distributes pharmaceutical or medical device products in the Philippines.
- 47 d. “Consultant” - means an external, independent healthcare professional, scientist,
48 patient association/patient representative, public or private payer retained individually
49 of through an entity (e.g., university, hospital or research organization) to provide
50 expert advice, information or other services.
- 51 e. “Disclosure” - means the release of material and relevant information.

- 1 f. "Events" - means congress, meetings, conventions, symposia, scientific events, and
2 third party conferences
- 3 g. "Healthcare Professionals" (HCP) - means any member of the medical, dental,
4 pharmacy or nursing profession or any other person who, in the course of his/her
5 professional activities, may prescribe, recommend, purchase, supply or administer a
6 health product.
- 7 h. "Inappropriate inducement" - means a remunerative arrangement intended to
8 inappropriately influence an HCP's medical decision- and product selection.
- 9 i. "Market Authorization Holder" – means any legal entity responsible for introducing a
10 product in the Philippine market and which has been granted authorization by the FDA
11 upon issuance of a Certificate of Product Registration (CPR).
- 12 j. "Marketing" - means product promotion, distribution, selling, advertising, product
13 public relations, and information services, including internet and social media.
- 14 k. "Mass media" – refers to any means or methods used to convey advertising messages
15 to the public such as television, radio, magazines, cinema, billboards, posters,
16 streamers, hand bills, leaflets, mails, and the like.
- 17 l. "Medical Representative" - means a person who represents any duly authorized
18 manufacturer or distributor of pharmaceutical products whose primary duty is to
19 introduce or reacquaint a product to the physician, dentist, pharmacist, veterinarian or
20 any other qualified person and which form part of their program for promotion like
21 describing its use, and other salient information relative to said pharmaceutical
22 product.
- 23 m. "Modest" - means moderate and not excessive. When used in relation to meals and
24 hospitality provided to HCPS, it means generally that the value of hospitality should
25 not exceed what the HCPS would be prepared to pay for personal purposes.
- 26 n. "Promotion" - means the practice of giving temporary additional value to a brand,
27 product, or service to achieve specific marketing objectives. "Promotion" includes the
28 distribution of free/sample-pharmaceutical products. (AO 65 s. 1989) It shall also refer
29 to all informational and persuasive activities by manufacturers and distributors, the
30 effect of which is to induce the prescription, supply, purchase and/or use of medicinal
31 drugs. (WHO 1988)
- 32 o. "Promotional item or aid" – means a non-monetary item given to HCPs **or an**
33 **organization** for a promotional purpose with minimum value and quantity which must
34 be relevant to the HCP work and not for personal benefit. **(Can it be changed to**
35 **promotional premium/gimmick to distinguish from other promo materials e.g.,**
36 **brochures, pamphlets, etc.)**
- 37 p. "Third Party Conference" - means a conference sponsored or conducted by or on
38 behalf of a professional association that is independent, of an educational or scientific
39 or policy-making nature and for the purpose of promoting scientific knowledge,
40 medical advancement or delivery of effective healthcare.

41 42 43 **V. ETHICAL STANDARDS/PRINCIPLES**

- 44
45 A. The Food and Drug Administration totally adopts in the Mexico City and the
46 Kuala Lumpur Principles as provided for in BC 023-2013 and BC 007 s 2014,
47 respectively.
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2 **B. Other Ethical Standards/Principles**
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4 1. Interactions with Healthcare Professional and Medical Societies
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- 6 A. No financial or material gifts or benefits shall be offered by any Company to a
7 health care professional or members of their families for the purpose of promoting
8 the Company's products. Sponsorships or foreign travels shall be governed by
9 specific provisions of this AO.
- 10 B. Refreshments and/or meals incidental to the main purpose of an event can only be
11 provided exclusively to the legitimate participants and must be modest and
12 reasonable. Companies are prohibited from paying expenses of accompanying
13 guests of HCPs.
- 14 C. Companies may provide promotional aids to HCPs provided these (a) are of
15 modest value; (b) are relevant to the practice of medicine or education of the
16 patients; and (c) do not subsidize normal routine operations. Promotional aids
17 should contain only the generic name of the product and/or the company name
18 and logo, and shall not include taglines or promotional claims. For OTS, the
19 brand name can be included.
- 20
- 21 1) Companies may occasionally provide items of medical utility to healthcare
22 institutions (including hospital departments but excluding private clinics of HCPs)
23 such as textbooks, subscriptions to medical journals or anatomical models, which
24 benefit patients or serve a genuine educational function for the HCP
- 25
- 26 2) Items of medical utility should be modest, cost of which shall not be more
27 than Php 5,000.00. These items may carry only the company logo.
- 28 3) Companies are not allowed to give HCPs any type of non-educational items,
29 even if of modest value.
- 30 4) Companies shall not provide HCPs with personal gifts such as cakes, cookies,
31 wine, flowers, chocolates, gift basket, holiday gifts, travel and entertainment
32 tickets, cash and gift cheques. **(companies provide gift basket/ department**
33 **which is a common Christmas tradition minimum value of 2500 php used**
34 **as raffle prizes. (some give birthday cakes)**
- 35
- 36 D. Companies may assist in the conduct of research activities of health care
37 professionals and/or healthcare-related institutions, provided, that the policies and
38 guidelines of the DOH, FDA and the National Ethical Guidelines for Health
39 Research, ed 2011, of the Philippine National Health Research system (PNHRS),
40 regarding such activities are strictly followed. Moreover, companies must respect
41 the integrity of research activities and not fund conduct or use such activities as a
42 means to disguise product promotion or prescription. All outcomes or results of
43 researches conducted shall be forwarded to FDA, regardless of whether the
44 outcomes were favorable or not.
- 45
- 46 E. Companies shall not be allowed to fund, sponsor, assist or participate in any fund-
47 raising activities of any medical society or health related institutions (e.g., fun
48 runs, sports tournaments, dinners, movie premieres, etc.).
- 49
- 50 F. The education of medical interns, residents and fellows-in-training is the sole
51 responsibility of the health training facility, and therefore, Companies should not
52 have any active participation during such activities, such as, provide financial,

1 material or other support, and/or act as registrars or lecturers during the conduct
2 of their educational activities.

3
4 G. Medical societies shall inform and provide FDA access to events and meetings
5 funded, in whole or in part, by companies to enable FDA to observe and monitor
6 compliance with this Order.

7
8 H. The FDA designated or authorized officer and/or staff shall be allowed entry to
9 the conventions, symposia and conferences as deemed necessary by FDA, to do
10 monitoring visits, utilizing FDA funds.

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12 2. Responsibilities of Companies

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14 A. The Market Authorization Holder (MAH), through the Company's chief
15 Executive Officer (CEO), Medical Director (MD), and Compliance Officer
16 (CO), shall be responsible for ensuring compliance with this Order, in the
17 marketing and promotion of its products. In the case of a Certificate of Listing
18 of Identical Drug Product (CLIDP), responsibility shall be with the CLIDP
19 holder through its CEO, MD and CO.

20 B. Companies shall see to the development and documentation of internal
21 compliance procedures within their organization to facilitate observance of the
22 APEC Principles and related Circulars and Orders issued by the FDA and
23 DOH.

24 C. Companies shall disclose information on any fees, grant, funding, donation or
25 sponsorship (financial or non-financial) given to any HCP, healthcare
26 institution, and medical or specialty society that might be requested by FDA.
27 Such disclosure may include a brief description of the nature and value of the
28 support, copies of contracts and fees for services. Contracts between
29 Companies and HCPs, healthcare related institutions, medical societies and
30 patient organizations must include provisions granting consent to disclose
31 such information in accordance with this AO.

32 D. Companies shall not feature any HCP in their commercial endorsements or
33 advertisements or promotions.

34 E. Companies shall provide FDA information on any form of assistance granted
35 to healthcare-related institutions (hospitals, private/public, HMOs, clinics,
36 including the nature and value of the assistance as well as details relating to
37 the purpose of the assistance.

38
39 3. Local or Foreign Travels

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41 Industry sponsorship of Healthcare Professionals to Events involving foreign/local
42 travel shall be allowed subject to the following conditions:

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44 1) The main purpose of the Event is to provide scientific or educational
45 information.

46
47 2) The travel is justified because: (a) a significant proportion of the invited
48 attendees (HCPs) is from outside of the sponsored HCP's place/country of
49 practice, and it makes greater logistical or security sense to hold the event in
50 another location/country; or b) the relevant resource or expertise that is the
51 object or subject matter of the event is located outside of the sponsored
52 HCP's place/country of practice.

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- 3) The venue for such event is appropriate and conducive to the educational or scientific objectives of the conference. No posh venues or resorts are allowed.
 - 4) The selection of the HCP should be unrelated to prescribing and sale of the company's products. The following criteria shall apply for HCP sponsorship:
 - a) The HCP's area of practice must be consistent with the therapeutic field covered at the meeting or event;
 - b) The HCP must be expected to receive education in the relevant medical or scientific area of his/her practice, and
 - c) The event for which the HCP will participate must be scientific in nature
 - 5) No entertainment, side trips or other social/leisure activities are offered or paid for by the company.
 - 6) The sponsoring company shall submit the following to FDA every 1st quarter of the following year a report on the sponsorship of HCPs to Events involving international travel containing the following information:
 - the purpose/objectives of the travel, including the name, description and date of the event
 - the names of the sponsored HCPs and their specialty/field of practice
 - the travel dates of the HCPs; and
 - the scope and estimated value of sponsorship shouldered by the company (e.g., travel, accommodations, meals, registration fee, etc.); and
 - If the recipient is employed by the government, the sponsored HCP shall make a post travel report to his respective agency, including appropriate recommendations.
 - 7) The sponsorship for travel of HCPs attending events as mere participants shall only be for Economy class. A company may sponsor an unlimited number of HCPs for local events, including company sponsored events and a maximum of 7-10 HCPs for events **involving international travel** at one time, provided that the event is related to the HCPs area of expertise. Accompanying guests or family members of the HCP shall not be entitled to any travel sponsorship, meals or other expenses.
 - 8) A company may sponsor an HCP **as a mere participant or delegate** to a medical congress or convention involving international travel only **twice** in any calendar year. Excluded from the scope of this provision are Company-organized events such as investigator's or advisory board meetings provided the travel is justified in accordance with this Order and **provided further that there is a service agreement between the HCP and the Company,**
 - 9) Any sponsorship given to a HCP must not be conditional upon an obligation nor an inappropriate inducement to prescribe, recommend, or promote any product.

1 product must include:
2

- 3 ■ brand name and generic name of the product (see Sec. D.1 above
4 for guidelines on the printing of the generic name)
- 5 ■ name, logo and address of the company marketing the product
- 6 ■ Note: “Full prescribing information available from ...”
7

8 D.3. On web pages, appropriate measures must be taken to assure access
9 to information is restricted to targeted audiences.

10
11 D.4 No healthcare professional or health worker shall promote, advertise or
12 endorse any drugs and medicines in quad media, in print or visual display.
13 (Rule 40, IRR of the Universally Accessible Cheaper and Quality
14 Medicines Act of 2008)
15

16 E. Correct Use of Quotations

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18 • Quotations, for example from medical literature, must not change or
19 distort either the meaning intended by the author or the significance of
20 the underlying work or study.
21
- 22 • All claims must represent accurately the content of the substantiating
23 sources. However, if an author’s statement is not in compliance with
24 this Order, the statement cannot be used. Direct quotes must be in
25 context and verbatim and if spoken words are quoted, written
26 permission from the author is required.
27
- 28 • Any information or quotation derived from publications must mention
29 the complete source (at least in a footnote), i.e., name of the author, title
30 of the publication, name of the journal, volume and page number, year of
31 publication.
32

33 F. Correct Use of Data from Clinical Studies

- 34
35 • When research data including data from clinical studies is being
36 used in promotional material it should represent a fair and balanced
37 reflection of the available knowledge regarding risk and benefits of
38 the product in the relevant setting.
39
- 40 • Data from in-vitro and animal tests should be clearly marked as such.
41
- 42 • The following information or a reference to where it can be found
43 should be included:
44
 - 45 ○ number of patients involved (n values).
 - 46 ○ dosage regimen.
 - 47 ○ duration of treatment.
 - 48 ○ trial design, e.g., double blind, randomized study.
 - 49 ○ clinical endpoints.
 - 50 ○ statistical significance.
 - 51 ○ reference to relevant publications.
52

1 G. Use of Visuals, Graphics and Tables
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- 4 • Visuals must be accurate and consistent with the text, must not contain misleading graphs, tables or artwork and should be in good taste in relation to the information conveyed.
 - 6 • Graphs and tables must be accurate and not misleading, and they should give a description of the axes. They must also be adequately referenced. Misleading scales or dimensions must not be used.
 - 9 • Copyright permission must be obtained and acknowledgement given where appropriate.
- 10
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12 H. Use of Unpublished Data
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- 14
- 15 • The use of unpublished data is permitted if referred to as “data on file”. All such data must be made available to HCPs on request. Therefore it should be on hand before the promotional material is published, and be kept for future reference.
 - 18 • Publications and manuscripts accepted for publication or in press must be on hand, in complete length, before the promotional material is printed.
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22 I. General Requirements Relating to Claims
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- 25 • All claims must be true and substantiated/referenced from sources that can be made available upon request.
 - 27 • One sided information, or any conclusive statement based on inadequate or truncated evidence is not permitted.
 - 29 • Superlatives, exaggerations, and hanging comparatives without unequivocal supporting data, which merely claim that a product is better etc., must not be used.
 - 31 • “Drug of first choice”, “No. 1” claims and the like, must be supported by current, adequate and relevant clinical evidence.
 - 33 • Unsupported comments about competitors or their products are not allowed.
- 35

36 J. Additional Requirements Relating to Comparative Claims
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38 In addition to the general requirements relating to claims, the following requirements relating to comparative claims must be respected:
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- 40
- 41 • Comparative claims are allowed when properly supported by data and in accordance with local regulations.
 - 43 • The comparative use of adverse drug reaction data in promotional material is recommended only as part of a comprehensive and fair comparison of drugs and if otherwise allowed.
 - 45 • Comparative superiority claims are allowed only if they are based on data from adequate and well-controlled clinical trials, and if they are consistent with the body of other clinical data.
 - 47 • Claims referring to differences in efficacy between drugs are permissible only if the difference is statistically significant ($p \leq 0.05$) and clinically relevant.
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1 K. Prohibited Words, Phrases and Activities

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3 The following is prohibited:

- 4
- 5 • Use of the word “safe” without proper qualification.
 - 6 • Use of the word “effective” without proper qualification.
 - 7 • The word “new” unless the product or indication has been
 - 8 available and generally promoted for not more than twelve (12)
 - 9 months.
 - 10 • Use of the words “non-toxic”, “no side effects”.
 - 11 • Unspecified, unreferenced claims about side effects and safety.
 - 12 • Absolute statements (i.e., the only product ..., no other
 - 13 product ... etc.) unless supported and referenced by
 - 14 scientific data.
 - 15 • Superlatives unless substantiated by scientifically sound
 - 16 and appropriately interpreted data.

17

18 6. Advertisements, Promotions and Use of Internet for Over-the-

19 Counter Products and Medical Devices

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21 Any promotion of a product through the internet shall be guided by current FDA and

22 Ads Standards Council (ASC) standards and regulations and relevant requirements of this

23 Order.

24

25 No ethical or prescription products may be promoted or advertised through social

26 media, including the internet **except in medical journals and publications solely**

27 **intended for medical and allied professions. (Sec. 3, BFA Regulation No. 5 s 1987).**

28

29 7. Transit Advertisements

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31 All transit advertisements shall comply with FDA regulations including those

32 prescribed in Land Transportation Franchising Regulatory Board (LTFRB)

33 Memorandum Circular 2013-005., which states conformance to the standards relative to

34 morality, decency and public safety and the Code of Ethics of the (ASC).

35

36 C. MONITORING and COMPLIANCE

37

38 A critical function of FDA is protection of public health through promotion of safe

39 and rational use of **medicines and other pharmaceutical and medical products..** As

40 embodied in RA 9711, only registered products are allowed to be promoted and

41 advertised by companies with valid licenses to operate (LTO). Advertisements shall

42 reflect information as contained in the approved current product labels and Summary of

43 Product Characteristics (SPC). Any claim must be substantiated by scientific evidence.

44

45 The FDA shall conduct the following activities relevant in regulating advertisements,

46 promotions and other marketing activities:

- 47
- 48 • Monitor published advertisements
 - 49 • Handle complaints about advertisements, promotions and other marketing
 - 50 activities except consumer complaints.
 - 51 • Enforce existing regulations relative to non-compliant promotions and
 - 52 advertisements.

- 1 • Conduct audit of all ASC approved promotions and advertisements of FDA
2 regulated products
3

4 As embodied in its mandate, the FDA shall monitor not only published materials but
5 any material prior to advertisement (vetting). Materials on any health product shall be
6 submitted for “vetting” prior to publication.
7

8 All promotional material provided to the HCPs should:
9

- 10 • Be accurate and not misleading
11 • Contain the proper reference to substantiate any claim
12 • State the balance between risks and benefits; and
13 • Be consistent with the approved label, Product Insert and Patient Information
14 Leaflet.
15

16 For purposes of implementation of this Order, the DOH through the FDA shall be
17 the lead agency responsible for the implementation and enforcement of this guideline.
18 The FDA shall establish a Compliance Unit and/or designate a Compliance Officer in
19 each Center/office, to oversee the implementation of this Order. A Compliance Officer
20 shall be appointed each for pharmaceutical products and medical device. For this purpose,
21 the Compliance Unit shall have the following functions:
22

- 23 • Review and approve all advertising, promotion or marketing materials
24 • Develop/update substantive and procedural guidelines for reviewing all
25 advertising, promotion or other marketing materials
26 • Monitor compliance to the regulations imposed under this Code in
27 collaboration with the Regional Enforcement Unit (REU).
28 • Issue a warning letter for companies with violations.
29

30 D. COMPLAINTS HANDLING PROCEDURE 31

32 1. Complaints of violation of this Order shall be filed with the FDA.
33 All complaints shall be in writing and must include the following in
34 accordance with Sec. 3 Art. IV, Book III of the IRR of RA 9711:
35

- 36 a) Name and address of the Complainant
37 b) Name of the Company in violation
38 c) Summary of the complaint describing the nature, date and place
39 of the violation, the section of this Order that was violated and
40 other relevant information
41 d) Copies of the materials/photos or other evidence of violation
42

43 2. Company associations may receive and resolve complaints between
44 or among its members, provided:
45

- 46 a) It submits to FDA its constitutional documents including an up-
47 to-date list of its member organizations
48 b) It establishes an committee for resolving such complaints
49 composed of independent members /experts that are not
50 employed, affiliated or involved in business transactions
51 (directly or through his/her organization) with any of its
52 member companies

1 c) It shall submit to FDA copies of its decision together with the
2 relevant attachments for filing and posting at the FDA website
3 as deemed applicable by FDA
4

5 3. An appeal to the decision of the industry association under paragraph
6 2 above may be filed with the FDA.
7

8 **E. SANCTIONS**

9

10 Any violation of this Order shall be meted with the following applicable
11 sanctions provided in the FDA Act of 2009 and its Implementing Rules and
12 Regulations (IRR), specifically:
13

14 Cancellation of any authorization granted by FDA and imposition of fines as
15 described therein. (Book I Art. III, Sec. 2-B). (penalties are too harsh)
16

17 Non compliance with the provisions stated in this Order shall entitle FDA to
18 impose the following applicable sanctions:
19

- 20 • First violation – warning letter
- 21 • Second violation - Fine of not less than one hundred and fifty thousand pesos
22 (P150,000) up to three hundred thousand pesos (P300,000) depending on the
23 gravity of the offense
- 24 • Third violation- Fine of not less than three hundred thousand (P300,000) up to
25 five hundred thousand pesos (P500,000) and suspension of product
26 registration or license to operate, depending on the gravity of the offense
- 27 • Fourth violation- Fine of not less than five hundred thousand pesos (P500,
28 000) up to one million pesos (P1, 000,000) and cancellation of product
29 registration or license to operate, depending on the gravity of the offense.
30

31 In all cases, and publication/posting at FDA website. (The FDA shall also
32 post/publish the decision on its website as it deems appropriate)
33

34 In the event that this Order is silent on possible infringements, the applicable
35 provisions of the Mexico City and KL Principles, the Consumer Act and the Ads
36 Standards Council ???will cover such.
37
38

39 **VI. IMPLEMENTATION ARRANGEMENTS**

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- 41 A. Industry associations and companies shall develop and implement their own
42 standards/codes for health product promotion aligned with the principles and
43 guidelines of this Order as the minimum standards and will form part of the
44 FDA application requirements for License to Operate (LTO).
- 45 B. Healthcare Professional and Healthcare Professional Organizations should
46 respect this Order and develop and implement (if existing) their Codes of
47 Ethics consistent with this Order.
48

49 **VII. REPEALING AND SEPARABILITY CLAUSE**

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1 All other orders, rules, regulations, and other related issuances inconsistent with or
 2 contrary to this Order are hereby repealed, amended, or modified accordingly. All provisions
 3 of existing issuances which are not affected by this Order shall remain valid and in effect.
 4

5 In the event that any provision or part of this Order is declared unauthorized or
 6 rendered invalid by any Court of law or competent authority, those provisions not affected by
 7 such declaration shall remain valid and effective.
 8

9 **VIII. EFFECTIVITY**

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 11 This Order shall take effect within 15 days after publication in two leading
 12 newspapers of general circulation, but sanctions will apply effective January 1, 2015. without
 13 prejudice to the enforcement of orders and regulations already existing and in effect prior to
 14 January 1, 2015.
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23 **ENRIQUE T. ONA, MD**
 24 Secretary of Health
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FDA Ethical Market Communications	Food and Drug Administration	Health Policy Development and Planning Bureau	Office of the Secretary
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