Note: This draft is only intended as a copy for comments during the stakeholder consultation period of the proposed guidelines. The content of this draft may change and does not prejudge any policy nor decision of the FDA. Citation of any text in this draft, for purposes other than the submission of comments as indicated in the issued announcement, is not recommended.

ADMINISTRATIVE ORDER

No. _____

SUBJECT : **Rules and Regulations Governing the Issuance of Authorizations for Toys and Childcare Articles**

I. RATIONALE

Through previous policies implementing Republic Act (RA) No. 7394, otherwise known as the "Consumer Act of the Philippines", the Department of Health (DOH) initially established the regulatory framework governing health products, particularly toys for children, through the then-Bureau of Health Devices and Technology. With the enactment of RA 9711 or the "Food and Drug Administration Act of 2009", the Food and Drug Administration (FDA) was strengthened, and the law aligned regulatory functions over health products of the Department to the created Health Product Centers of the FDA. Thereafter, through the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), the FDA implemented regulatory processes ensuring the safety, efficacy and quality of household/urban hazardous substances, including toys and articles intended for children.

In 2015, the FDA promulgated guidelines to streamline the authorization processes for toys and childcare articles through a product notification procedure, which also placed emphasis on the responsibility of market authorization holders (MAH) to ensure compliance with FDA-instituted standards. Updates to toy safety regulation were further introduced in 2019 by way of the Implementing Rules and Regulations (IRR) of RA 10620, otherwise known as the "Toy and Game Safety Labelling Act of 2013" which introduced special labeling requirements for toys and games.

A review of the existing regulatory framework for toys and articles intended for children revealed gaps in the policies and guidelines, including the need to update labeling requirements to be consistent with the IRR of RA 10620, the need to address the incongruency of the requirements for the issuance of certifications for exempted toys, and the need to update standards to ensure the safety of toys and childcare articles. Hence, this Order is hereby issued to provide the updated rules and regulations governing the issuance of authorizations for toys and childcare articles.

II. OBJECTIVES

This Order aims to establish the rules and regulations governing the issuance of authorizations for toys and childcare articles (TCCA). Specifically, it aims to:

A. Update and align TCCA regulations with appropriate laws, locally-established standards, and internationally-accepted standards;
B. Institutionalize the Product Notification procedure for toys and childcare articles;
C. Rationalize the issuance of Certificates of Exemption for exempted toys, games, and childcare articles; and,
D. Provide the roles and responsibilities of marketing authorization holders in ensuring the safety, efficacy, and quality of toys and childcare articles throughout the product life cycle.

III. SCOPE

This Order covers all establishments engaged in the manufacture, packing, repacking, importation, exportation, sale, offer for sale, distribution, transfer, use, testing, promotion, advertising, and sponsorship of toys and articles intended for use by children less than fourteen (14) years of age.

IV. DEFINITION OF TERMS

For the purposes of implementing this Order, the following terms are defined as follows. Other terms used shall have the same meaning as defined in RA 9711 and its IRR.

A. Certificate of Product Notification- an authorization secured by a TCCA establishment from the FDA for its intention to place a particular TCCA product in the local market

B. Certificate of Exemption – an authorization issued by the FDA to an entity importing TCCA products for the limited purposes of display, exhibit or donation, without any intention to be sold in the Philippine market

C. Foreseeable use- play modes that conform to the instructions that accompany the toy, that have been established by tradition or custom, or that are evident from an examination of the toy. This term shall also refer to as apparent use.

D. License to Operate- authorization issued by FDA to an establishment to grant permission to undertake a trade or carry out a business activity, such as the manufacture, distribution, importation, exportation, sale, offering for sale, or transfer of toys and childcare articles

E. Market Authorization Holder- is the owner on the marketing authorization issued by FDA for a specific health product

F. Re-export- the act of sending imported goods to another country.

G. Toys and childcare articles – articles intended for use by children less than fourteen (14) years of age that the FDA may determine to pose an electrical, chemical, physical, or thermal hazard.

H. TCCA products for personal use – refer to TCCA products whether new or used in non-commercial quantities for purposes of personal use or consumption and not for commercial purposes. Commercial quantities shall refer to the quantity for a given kind or class of articles that are in excess of what is compatible with and commensurate to the person's normal requirements for personal use.

V. GENERAL GUIDELINES

A. Establishments engaged in the manufacture, packing, repacking, importation, exportation and distribution of toys and articles intended for use by children less than fourteen (14) years of age shall secure a License to Operate (LTO) from the FDA before the commencement of such activities. A Certificate of Product Notification (CPN) for the TCCA product shall likewise be secured from the FDA by the licensed establishment prior importation and/or being placed in the market.

B. The labeling and packaging of TCCA products shall be in adherence with the labeling requirements adopted by the FDA, consistent with RA 7394, RA 10620, and their IRR and future amendments.

C. TCCA products, including the chemicals they contain, must not jeopardize the safety and health of children and users when used as intended or in a foreseeable way, bearing in mind the behavior of children. Further, TCCA products shall be in compliance with applicable product standards adopted by the DOH and the FDA, including but not limited to safety standards in relation to their physical, mechanical, electrical, chemical, or thermal properties. Furthermore, TCCA products must be free from substances banned by the DOH and the FDA and/or must not contain ingredients restricted by the DOH and the FDA in concentrations exceeding allowable limits. Further, lastly, no claim shall be made in labeling, advertisements, marketing and promotional materials that implies that a TCCA product has characteristics it does not have.

D. The primary responsibility of ensuring the safety, efficacy, and quality of TCCA products covered by this Order shall rest upon the market authorization holder (MAH). Establishments engaged in the sale of TCCAs declared by the FDA to be injurious, unsafe, or dangerous shall be required to immediately recall, withdraw, seize, or ban the sale, distribution, or donation to the public. Any TCCA product, the sale or use of which has been banned or withdrawn in the country of manufacture, shall not be imported into the country. The FDA shall not be precluded from issuing the necessary notices and/or warnings in order to prevent the purchase and use of injurious, unsafe, dangerous, or mislabeled TCCA products.

E. Any untoward incident involving TCCA products resulting in the death, serious illness or injury, medical treatment of a child shall be reported by the manufacturers, traders, distributors, importers, and/or the MAHs to the FDA immediately and within prescribed timeframes. Non-serious untoward incidents and safety concerns involving TCCA products shall likewise be reported to the FDA.

F. The FDA shall conduct postmarketing surveillance (PMS) activities on TCCA establishments and products to monitor compliance with this Order, and other

applicable FDA rules, regulations and standards. Further, the FDA shall not be precluded to undertake any regulatory action, following due process, upon entities found to be in violation of RA 9711, RA 7394, RA 10620, and other applicable laws, rules and regulations, in order to ensure consumer protection and public health and safety.

VI. SPECIFIC GUIDELINES

A. Definition and Classification of TCCAs

1. TCCA products shall be classified according to age group and use, as follows:
    a. Toys intended for children below 14 years of age
    b. Swings, slides, and similar activity toys for indoor and outdoor family domestic use
    c. Childcare articles designed or intended by the manufacturer to facilitate sleep, feeding, and hygiene that comes directly in contact with the mouth, or to help children with sucking or teething

2. Products shall be classified consistent with the definitions provided in this Order. The product presentation, including the age category of users, intended and apparent use, design, claims, of the TCCA product shall be considered in this determination.

3. **Annex A** provides an illustrative list of currently identified TCCA products. Currently unimagined product forms and types shall be considered against the definition of a TCCA product.

4. The FDA shall have the authority to create additional classes, classify or reclassify products that will be considered as TCCA Products, consistent with this Order, and in pursuit of public health and safety.

B. Licensing of TCCA Establishments

1. Establishments shall be classified according to their licensed activity(ies), namely:
    a. Manufacturers, Manufacturer/Packers, Manufacturer/Repackers;
    b. Traders; and,
    c. Distributor/Importers, Distributor/Exporters, Distributor/Wholesalers, or a combination thereof.

2. The requirements and the procedure for filing an LTO application shall be in accordance with DOH Administrative Order (AO) No. 2020-0017 and its amendments.

3. Establishments shall comply with applicable standards, including but not limited to Good Manufacturing Practices (GMP), Good Distribution and

Storage Practices (GDSP), and other standards promulgated and/or adopted by the FDA, in the conduct of their licensed activity/ies.

4. The FDA shall have the authority to enter any covered establishments engaged in FDA-regulated activities involving TCCA products during operating hours to conduct routine or spot check inspections.

C. Market Authorization of TCCA products

1. FDA-licensed manufacturers, traders, packers, repackers and distributors shall signify their intent to introduce a toy and/or childcare article in the Philippine market through the filing of an application for CPN. Only TCCA with valid CPNs by the FDA may be imported and/or placed in the Philippine market.

2. The procedure for filing an application for a CPN for TCCAs shall be in accordance with the latest guidelines issued by the FDA.

    a. The requirements which shall be submitted in support of the application are listed in **Annex B**.
    b. The product standards applicable for TCCA products are listed in **Annex C**.
    c. The labeling and packaging requirements for TCCA products are listed in **Annex D**.

    A CPN shall be issued upon an application that has satisfactorily complied with all applicable requirements and standards. The validity of TCCA authorization shall vary depending on the length applied, i.e., 1, 2, or 3 years. Any changes to the product information submitted in support of a CPN application shall constitute a new application.

3. Any of the following or similar instances shall be a ground for the disapproval of an application, suspension, revocation or cancellation of the authorization, following Book II, Article I, Section 4.B of the IRR of RA 9711:

    a. The application requirements submitted show that the establishment does not meet the required technical requirements or appropriate standards;
    b. The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law or existing FDA rules and regulations or appropriate standards;
    c. The holder or owner has violated any of the terms and conditions of its authorization;
    d. The label of the health product is false and misleading or does not conform with current labeling requirements;
    e. The holder or owner of the CPR/authorization, without legitimate reason fails to sell the health product or fails to cause it to be marketed during

an uninterrupted period of at least three (3) years from date of issuance or renewal of the registration, or the last date of operation or marketing;

f. Such analogous grounds or causes as determined by the FDA.

Nothing in this section shall restrict the FDA from imposing the penalty of suspension, revocation, or cancellation of registration or authorization for administrative violations of any other relevant laws or their implementing rules and regulations.

D. Postmarketing surveillance of TCCA products

1. The primary responsibility of ensuring the safety, efficacy and quality of TCCA products covered by this Order shall rest upon the MAH. Notified TCCA products shall continuously comply with the product standards instituted by and as updated by the FDA. The MAH shall ensure that no claim shall be made in labeling, advertisements, marketing and promotional materials that implies that a TCCA product has characteristics it does not have.

2. Establishments engaged in the sale of TCCAs declared by the FDA to be injurious, unsafe, or dangerous shall be required to immediately recall, withdraw, seize, or ban the sale, distribution, or donation to the public. Any TCCA product, the sale or use of which has been banned or withdrawn in the country of manufacture, shall not be imported into the country. For this purpose, a product recall procedure shall be developed and maintained by the MAH, as part of its overall Risk Management Plan. Further, the MAH shall observe and comply with the guidelines on the conduct of product recall under FDA Circular No. 2016-012 and its amendments.

3. Any untoward incident involving TCCA products resulting in the death, serious illness or injury, medical treatment of a child shall be reported to the FDA. The MAH shall report to the FDA such untoward incidents within two (2) working days upon first knowledge.

   Non-serious untoward incidents involving TCCA products shall likewise be reported to the FDA by the MAH within fifteen (15) days upon first knowledge.

4. The FDA shall develop a reporting platform to receive complaints, including safety concerns from the public.

5. The FDA shall conduct postmarketing surveillance (PMS) activities, including but not limited to the sampling, collection, verification of products in the market, inspection of TCCA establishments, recall effectiveness audits. and testing of products, to monitor compliance with this Order, and other applicable FDA rules, regulations and standards. Further, the FDA shall not be precluded to undertake any regulatory action, following due process, upon entities found to be in violation of RA 9711, RA 7394, RA 10620, and other applicable laws, rules and regulations, in order to ensure consumer protection and public health and safety.

E. Rules for TCCA products intended for specific purposes

The following rules shall apply to TCCA products which are not intended to be placed in the Philippine market:

1. Imported TCCA products intended for donation, charity and missionary work shall comply with the guidelines provided under DOH Administrative Order No. 2020-0001 and its amendments.

2. TCCA products which are intended solely for the purpose of display/exhibition may be imported; Provided, that the imported product shall not be offered for sale; Provided, further, that the imported product shall be re-exported or disposed after display/exhibition; Provided, lastly, that the importing entity secures a Certificate of Exemption from the FDA. Individuals and entities importing such toys and games shall adhere to the conditions granted under the issued certification.

3. Manufacturers and distributor/exporters of TCCA products intended solely for export and re-export shall secure an LTO from the FDA. However, a CPN for such TCCA products shall no longer be required.

   Further, establishments exporting and/or re-exporting such TCCA products shall bear the overall responsibility for the safety, efficacy and quality of their products. Furthermore, such establishments shall be responsible for any necessary compliance with the standards and regulations of the receiving country or state.

4. Individuals importing TCCA products for personal use shall be exempted from securing prior clearance from the FDA; Provided, that such products are imported in quantities not exceeding the limits set and following conditions specified in DOH-FDA-Bureau of Customs (BOC) Joint Circular No. 1-2015 and its subsequent amendments.

   Further, individuals shall assume full responsibility over the use of such imported TCCA products. Any untoward incidents arising from the use of such imported TCCA products shall be immediately reported to the FDA the described timeframes consistent with Item no. 3 of Section VI.D; wherein, such individuals shall fully cooperate with the FDA and other relevant authorities on corrective actions which will be required.

VII. ROLES AND RESPONSIBILITIES

A. TCCA Manufacturers, Traders, Packers, Repackers and Distributors

1. The MAH shall ensure continuous compliance with these Guidelines, including the established product standards, technical, labeling, and packaging requirements set by the DOH and the FDA, to guarantee the safety and quality of the notified TCCA products.

2. Manufacturers, Packers, and Repackers shall observe Good Manufacturing Practices in the manufacture of TCCA products.
3. Manufacturers, Packers, Repackers, and Distributors shall observe Good Distribution and Storage Practices in the distribution of TCCA products across the supply chain.
4. The MAH shall be responsible for conducting the proper monitoring and investigation of reported untoward incidents related to the usage of TCCA products.
5. The MAH shall be responsible for reporting to the FDA any untoward incidents within the prescribed timeframes provided in this Order and in accordance with further implementing guidelines issued by the FDA.
6. The MAH shall initiate necessary measures for the immediate recall and discontinuation of the sale and/or distribution of TCCA products deemed to be injurious, unsafe, dangerous, or grossly deceptive. Incidental costs emanating from the aforementioned safety measures shall be borne by the MAH. Recalls conducted by the MAH shall be in compliance with product recall guidelines under FDA Circular No. 2016-012 and its future amendments.
7. The MAH shall fully cooperate with the FDA in the conduct of PMS activities, and shall be responsible for timely carrying out corrective and preventive action plans for identified non-conformities and deficiencies against standards.

B. TCCA Retailers

1. Retailers shall ensure that TCCA products sold or offered on sale in their establishments or platforms, including physical and online, are supplied through licensed TCCA Manufacturers and/or Distributors.
2. Retailers shall take measures to verify that TCCA products sold or offered on sale in their establishments or platforms are duly-notified with the FDA and bear the appropriate labeling and packaging requirements.
3. TCCA Retailers shall cooperate with the FDA in the conduct of PMS activities, including the recall, return, and/or quarantine of TCCA products deemed to be injurious, unsafe, dangerous, or grossly deceptive. Retailers shall remove violative products from their shelves and take down products from their platforms in accordance with issued advisories, warnings and/or orders by the FDA.

C. FDA

1. The FDA shall issue the necessary guidelines, including transitory arrangements, to effectively implement this Order.
2. In addition to the requirements and standards in the Annexes, the FDA may require additional technical and administrative requirements and introduce updates to the standards, including those not covered by this Order, provided that these shall be issued in the form of FDA Circulars, in order to ensure the effective implementation of this Order.
3. The FDA shall keep a record of licensed establishments and notified TCCA products pursuant to this Order on its FDA website, which shall be accessible to consumers and other concerned stakeholders.

4. The FDA shall develop and implement a PMS plan, which shall allow the monitoring of the continuous compliance of TCCA establishments and products with this Order.
5. The FDA shall issue the necessary appropriate public health warnings and/or advisories for stakeholders and the public, pursuant to its conducted PMS activities wherein violations of existing rules and regulations and/or risks to public health and safety are found.

VIII. TRANSITORY PROVISIONS

A. The FDA shall issue implementing rules or guidelines for the provisions stated herein within six (6) months of the effectivity of this Order.

B. Affected stakeholders shall be provided a transitory period of not more than six (6) months from the date of effectivity of the implementing rules or guidelines of this Order to allow covered establishments to comply with the new guidelines.

IX. PENALTY CLAUSE

Any person and/or establishment found in violation of this Order shall be deemed a violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

X. REPEALING CLAUSE

Administrative Order No. 2009-0005 and its amendments, FDA Circular No. 2015-002 are hereby repealed. Other related issuances inconsistent or contrary to the provisions of this Administrative Order are hereby amended or modified accordingly.

XI. SEPARABILITY CLAUSE

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

XII. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the University of Philippines Office of the National Administrative Register.

TEODORO J. HERBOSA, MD
Secretary of Health

Office	**FDA**	**COS**
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Date		

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