NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS (PROHIBITION) REGULATIONS 2019

ARRANGEMENT OF SECTIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

1. **Scope**

   These Regulations shall apply to the use of non-nutritive sweeteners in drug products that are manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

2. **Prohibition**

   (1) No person shall;

   (a) Manufacture, import, export, advertise, sell, display for sale, offer for sale or distribute, cause to be distributed or use any drug product which contains non-nutritive sweeteners, except as provided for in these Regulations

   (b) No person shall manufacture, import, export, advertise, sell, distribute, or cause to be distributed or use any drug product which contains non-nutritive sweeteners which are recognized as novel excipients.

3. **Adulterated Products**

   A drug product shall be deemed as adulterated and hazardous to health, if it contains non-nutritive sweeteners not permitted by the Agency.

4. **Conditions of use of non-nutritive sweeteners**

   Without prejudice to Regulation 2 of these Regulations, the Agency may authorize the manufacture, importation, exportation, sale, distribution, advertisement and use of registered or permitted non- nutritive sweeteners for special dietary requirements and drug formulations.

5. **Penalty.**

   (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :

   (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and

   (b) a body corporate, to a fine not exceeding N100, 000.

   (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-

   (a) director, manager, secretary or other similar officer of the body corporate; or

(b) partner or officer of the firm or
(c) trustee of the body concerned ;or
(d) person concerned in the management of the affairs of the association ;or
(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

6. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
(b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

7. **Interpretation**

(1) For the purpose of these regulations unless the context otherwise requires, the following words mean:-

"Adulterated drug" means a drug product which contains non-nutritive sweetener(s) not permitted by the Agency;

"Agency" means National Agency for Food and Drug Administration and Control;

"**Drug**" includes any substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in:
(a) the diagnosis, treatment, mitigation, in man or animal;
(b) restoring, correcting or modifying organic function in man and animal;
(c) disinfections or the control of vermin, insects or pest; or
(d) contraception;

"Non-nutritive sweetener" means any substance having non-nutritive properties, which when added to a product is capable of imparting sweetness to the product.

"Novel excipient" means any substance which is used as an excipient to impart sweetness for the first time in a drug product, or by a new route of administration.

8. **Repeal of Non-Nutritive Sweeteners (Prohibition) Regulations 2005**
   (1) The Non-Nutritive Sweeteners in Drug Products (Prohibition) Regulations 2005 is hereby repealed.
   (2) The repeal of these Regulations specified Regulation 8 (1) shall not affect anything done or purported to be done under the repealed Regulations.

9. **Citation**
   These Regulations may be cited as Non-Nutritive Sweeteners in Drug Products (Prohibition) Regulations 2019.

SCHEDULE 'A'

MAXIMUM LEVELS OF NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS

SWEETENER	PHARMACOPOEIA	ACCEPTABLE DAILY INTAKE (ADI)
Acesulfame potassium	BP, Ph. Eur., USP-NF	15mg/kg body-weight
Aspartame	BP, Ph. Eur., USP-NF	40mg/kg body-weight
Neotame	USP-NF	2mg/kg body-weight
Saccharin	BP, JP, Ph. Eur., USP-NF	2.5mg/kg body-weight

*Accepted Daily Intake (ADI) Limits set by World Health Organization (WHO)

Made at Abuja this …….Day of……2019

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)