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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS (PROHIBITION) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 81 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS (PROHIBITION) REGULATIONS, 2021

[*7th Day of July,* 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other 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 Minister of Health makes the following Regulations—

1. 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. Scope of application.

2. A person shall not manufacture, import, export, advertise, sell— Prohibition.

(*a*) 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 ; and

(*b*) manufacture, import, export, advertise, sell, distribute, or cause to be distributed or use any drug product which contains non-nutritive sweeteners, which are recognised as *novel excipients*.

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

4.—(1) Without prejudice to regulation 2 of these Regulations, the Agency may authorise the manufacture, importation, exportation, sale, distribution, advertisement and use of registered or permitted non- nutritive sweeteners for special dietary requirements and drug formulations. Conditions for the use of non-nutritive sweeteners.

(2) The use of non-nutritive sweeteners shall be as specified in the Schedule to these Regulations.

5.—(1) A person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction, in the case of— Offences and Penalties.

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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 ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for that offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

6. A person convicted of an offence under these Regulations shall forfeit to the Federal Government of Nigeria—

(*a*) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; or

(*b*) any of the person's property or instrument used in any manner to commit or to facilitate the commission of the offence.

Revocation.

7.—(1) The Non-Nutritive Sweeteners in Drug Products (Prohibition) Regulations, 2005 is hereby revoked.

(2) The revocation of the Regulations specified in sub-regulation (1) of this regulation shall not affect anything done or purported to have been done under the revoked Regulations.

Enforcement of these Regulations.

8. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

9. In these Regulations—

"*Adulterated drug*" means a drug product which contains non-nutritive sweetener 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 of it manufactured, sold or advertised for use in—

(*a*) the diagnosis, treatment, mitigation, of aperson or animal,

(*b*) restoring, correcting or modifying organic function in man and animal,

(*c*) disinfections or the control of vermin, insects or pests, 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 ; and

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of the offence.

10. These Regulations shall be cited as Non-Nutritive Sweeteners in Drug Products (Prohibition) Regulations, 2021. **Citation.**

SCHEDULE

[*Regulation* 4 (2)]

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

MADE at Abuja this 7th day of July, 2021

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health