WORLD TRADE ORGANIZATION

G/TBT/N/IDN/153

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** INDONESIA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Indonesian Food and Drug Authority (FDA) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Bureau for Cooperation and Public Relations Indonesian Food and Drug Authority (FDA) Jl. Percetakan Negara No.23 Jakarta 10560 – Indonesia Telephone : +(62-21) 42875379 Facsimile : +(62-21) 42875379 Email : kerjasama@pom.go.id Website : http://www.pom.go.id Directorate of Implementation System for Standards and Conformity Assessment National Standardization Agency of the Republic of Indonesia (BSN) TBT WTO Notification and Enquiry Point of Indonesia Gedung 2 Laboratorium SNSU BSN, Komplek Puspiptek, Muncul, Tangerang Selatan, Banten 15314 Email: tbt.indonesia@bsn.go.id and tbt.indonesia@gmail.com Website: http://www.bsn.go.id
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Drug Materials, Traditional Drug Materials, Cosmetic Materials, Health Supplement Materials, Food Materials.
5.	**Title, number of pages and language(s) of the notified document:** Indonesian FDA Regulation No. 26 of 2022 on Supervision of the Importation of Drug and Food Materials into Indonesian Territory; (23 page(s), in Indonesian)
6.	**Description of content:** This regulation is the amendments to Indonesian FDA Regulation No. 29 of 2017 on Supervision of the Importation of Drug and Food Materials into Indonesian Territory. New provisions changed on this regulation include: a. Additional regulation on the entry of certain drug materials (Propylene Glycol, Polyethylene Glycol and other materials with limited levels of Ethylene Glycol and Diethylene Glycol for pharmaceutical grade) through Post Border Import Notification Letter (Surat Keterangan Impor) mechanism.

b. The amendment of the operational definition of Border Import Notification Letter and Post Border Import Notification Letter.

c. The adjustment of Special Access Scheme mechanism under Indonesia FDA supervision such as for Biological Products; Research Drugs (excluding Biological Products, narcotics, psychotropics and pharmaceutical precursors); and Drug Materials.

d. The amendment of the provision of importation realization report submitted by business actors.

e. The addition of several drug materials to the list of drug materials attachments which is supervised by Indonesia FDA.

7. **Objective and rationale, including the nature of urgent problems where applicable:** As guidelines for The Importation of Drug and Food Materials into Indonesian Territory; Protection of human health or safety

8. **Relevant documents:**

1. Law Number 10 of 1995 regarding Customs and Excise Affairs (State Gazette of the Republic of Indonesia year 1995 Number 75, additional State Gazette of the Republic of Indonesia Number 3612) as amended by Law Number 17 of 2006 regarding the amendments to Law Number 10 of 1995 regarding Customs and Excise Affairs (State Gazette of the Republic of Indonesia year 2006 Number 93, additional State Gazette of the Republic of Indonesia Number 4661);
2. Presidential Regulation Number 80 of 2017 concerning the Drug and Food Control Agency (State Gazette of the Republic of Indonesia year 2017 Number180);
3. Indonesian FDA Regulation Number 21 of 2020 on the Organization and Work Procedure of Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia year 2020 Number 1002) as amended by Indonesian FDA Regulation Number 13 of 2022 on the amendments to Indonesian FDA Regulation Number 21 of 2020 on the Organization and Work Procedure of Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2022 Number 629);
4. Indonesian FDA Regulation Number 22 of 2020 on the Organization and Working procedure of Technical Implementation Unit within the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2020 Number 1003) as amended several times, the lates by Indonesian FDA Regulation Number 24 of 2022 on the second amendments to Indonesian FDA Regulation Number 22 Year 2020 the Organization and Working procedure of Technical Implementation Unit within the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2022 Number 1111);
5. Indonesian FDA Regulation Number 23 of 2020 on the Organization and Working procedure of Technical Implementation Unit within the Indonesian FDA National Quality Laboratory of Drug and Food (State Gazette of the Republic of Indonesia Year 2021 Number 1004);
6. Indonesian FDA Regulation Number 10 of 2021 on Standards for Business Activities and Products on the Implementation of Risk-Based Business Licensing for the Drug and Food Sector (State Gazette of the Republic of Indonesia Year 2021 Number 292).

9. **Proposed date of adoption:** 14 November 2022

Proposed date of entry into force: 14 December 2022

10. **Final date for comments:** 60 days after notification.

11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** https://members.wto.org/crnattachments/2023/TBT/IDN/23_09447_00_x.pdf