Notification of the Office of the Food and Drug Administration
re: No Requirement for Applicants for a Medical Device Manufacturing License or a Medical Device Import License to Submit Information, Documents, or Evidence as Required by the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License
B.E. 2564 (2021)

To prevent a shortage of medical devices, and to facilitate applications for permission to manufacture or import medical devices, during the period of adjustment to risk levels with regard to the control over medical devices pursuant to the Medical Device Act (No. 2), B.E. 2562 (2019), applicants are not required to submit information, documents, or evidence under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020, as reasonable and necessary.

By virtue of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020, the Secretary-General of the Food and Drug Administration issues the following Notification.

Clause 1 Registrants of establishments involved in the manufacturing of medical devices whose registration certificates expire on 31 December 2021, or registrants of establishments involved in the import of medical devices whose import certificates will expire no later than one year after this Notification takes effect wishing to modify the level of control over medical devices, in accordance with the Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which the Manufacturers and Importers Must Obtain License, B.E. 2563 (2020) dated 29 December 2020, shall submit their applications to the licensor without having to provide the following information, documents, or evidence.

(1) Summary of medical devices as required under clause 2(3) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(2) Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity, as required under clause 2(4) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(3) Summary of design verification and validation documents, as required under clause 2(5) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(4) Documentation showing risk analysis, as required under clause 2(6) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(5) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(6) Certification of quality systems as required under clause 2(8) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(7) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(8) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(9) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(10) Certification of permission issued by authorities in charge of, and with the power to engage in the supervision over medical devices in the relevant foreign country accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

Clause 2 Registrants of establishments involved in the manufacturing or import of medical devices other than those indicated in clause 1 or clause 3 who wish to apply for licenses shall submit their applications to the licensor without providing the following information, documents, or evidence, within three years after the date this Notification takes effect.

(1) Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity, as required under clause 2(4) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(2) Summary of design verification and validation documents, as required under clause 2(5) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(3) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(4) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(5) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(6) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

(7) Certification of permission issued by authorities in charge of, and with the power to engage in the supervision over medical devices in the relevant foreign country accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

However, if the applicant has any documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020, he or she must submit the documentation together with the application.

Clause 3 For registrants of establishments involved in the manufacturing or import of any of the following medical devices who wish to apply for licenses:

(1) HIV-related test kits pursuant to the Notification of the Ministry of Public Health re: HIV-Related Test Kits, dated 2 November 2009, and the Notification of the Ministry of Public Health re: HIV-Related Test Kits (No. 2), B.E. 2562 (2019), dated 19 March 2019;

(2) test kits in connection with HIV self-tests pursuant to the Notification of the Ministry of Public Health re: Test Kits in Connection with HIV Self-tests, B.E. 2562 (2019), dated 19 March 2019;

(3) hyaluronic acid to treat skin problems pursuant to the Notification of the Ministry of Public Health re: Hyaluronic Acid Injection to Treat Skin Problems, B.E. 2562 (2019), dated 9 August 2019;

(4) silicone for breast implants pursuant to the Notification of the Ministry of Public Health re: Silicone for Breast Implants, B.E. 2562 (2019), dated 7 November 2019;

(5) blood bags, pursuant to the Notification of the Ministry of Public Health re: Human Blood Bags, dated 9 March 2016;

(6) condoms, pursuant to the Notification of the Ministry of Public Health re: Condoms, B.E. 2556 (2013) dated 18 September 2013; or

(7) viscoelastic substances used in eye surgeries, pursuant to the Notification of the Ministry of Public Health re: Viscoelastic Substances Used in Eye Surgeries, B.E. 2557 (2014), dated 24 November 2014;

To submit their applications to the licensor in accordance with the first paragraph, the following information, documents, and evidence are not required for three years after the date this Notification takes effect.

1) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

2) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

3) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

4) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

5) Certification of permission issued by authorities in charge of, and with the power to engage in the supervision over medical devices in the relevant foreign country accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

However, if the applicant has information, documents, or evidence indicated in the second paragraph, the information, documents, or evidence must also be submitted.

Clause 4 Any declarer of specifications regarding the manufacturing or import of viscoelastic substances used in eye surgeries, which are categorized as groups of medical devices or medical devices that require license under the Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which the Manufacturers and Importers Must Obtain License, B.E. 2563 (2020), dated 29 December 2020, before this Notification takes effect, and wishing to continue their business must submit their applications under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020, before the receipt of specifications expires. In this case, no information, documents, or evidence indicated in clause 2 of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020, is required.

If an application has been submitted within the specified timeframe, the licensor will issue a license, and the documents supporting the specifications that have already been submitted will be deemed to support the permission under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

Clause 5 Any applicant wishing to renew their medical device manufacturing license or medical device import license under this Notification, must summit complete information, documents, and evidence, as prescribed in clause 2 of the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), dated 22 December 2020.

Clause 6 This Notification takes effect from the date of its publication in the *Government Gazette*.

Issued on 2 February 2021

Paisarn Dunkum

Secretary-general of the Food and Drug Administration