(Form No.20)

**MINISTRY OF HEALTH, LABOUR AND WELFARE**

**GOVERNMENT OF JAPAN**

**2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916**

No. of Statement Exporting Country: Japan

Importing Country:

Statement of Licensing [Approval and Licensing] Status of Pharmaceutical Product(s) 1

This statement indicates only whether or not the following products are licensed [approved] to be put on the market in the exporting country.

Applicant Name:

Address:

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Product | Dosage form | Active ingredient(s) 2 and amount(s) per unit dose | Product licence No. and date of issue 3 [Product approval No. and date of manufacturing licence] |
|  |  |  |  |

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product licence holder [product approval and manufacturing licence holder]), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

Address of certifying authority: Pharmaceutical Safety Bureau

Ministry of Health, Labour and Welfare of Japan

2-2, Kasumigaseki 1-chome

Chiyoda-ku

Tokyo 100-8916

Name of authorized person:（医薬品審査管理課長（医療機器審査管理課長)の氏名）

Director,（担当課の名称）

Pharmaceutical Evaluation Division/ Medical Device Evaluation Division

Telephone number: +81-3-3595-2431 / +81-3-3595-2419

Fax number: +81-3-3597-9535 / +81-3-3597-0332

Signature:

Stamp and date:

This statement conforms to the format recommended by the World Health Organization (general instructions and explanatory note attached).

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1. This statement is intended for use by importing agents who are required to screen bids made in response to an international tender and should be requested by the agent as a condition of bidding. The statement indicates that the listed products are authorized to be placed on the market for use in the exporting country. A Certificate of a Pharmaceutical Product in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product licence holder [product approval and licence holder], for each of the listed products.

2　Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

3　If no product licence [product approval and manufacturing licence] has been granted, enter “not required”, “not requested”, “under consideration” or “refused” as appropriate.