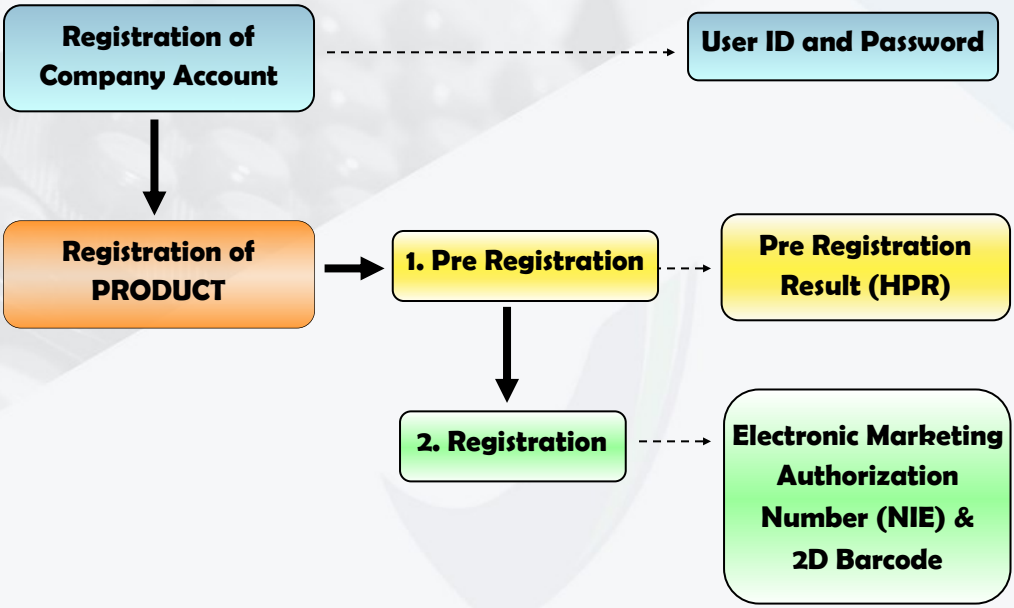
BADAN POM

GUIDANCE BOOK FOR THE REGISTRATION OF NATURAL MEDICINES, QUASI DRUGS, AND HEALTH SUPPLEMENTS

Directorate of Traditional Medicines, Health Supplements, and Cosmetics Registration

Indonesian Food and Drug Authority

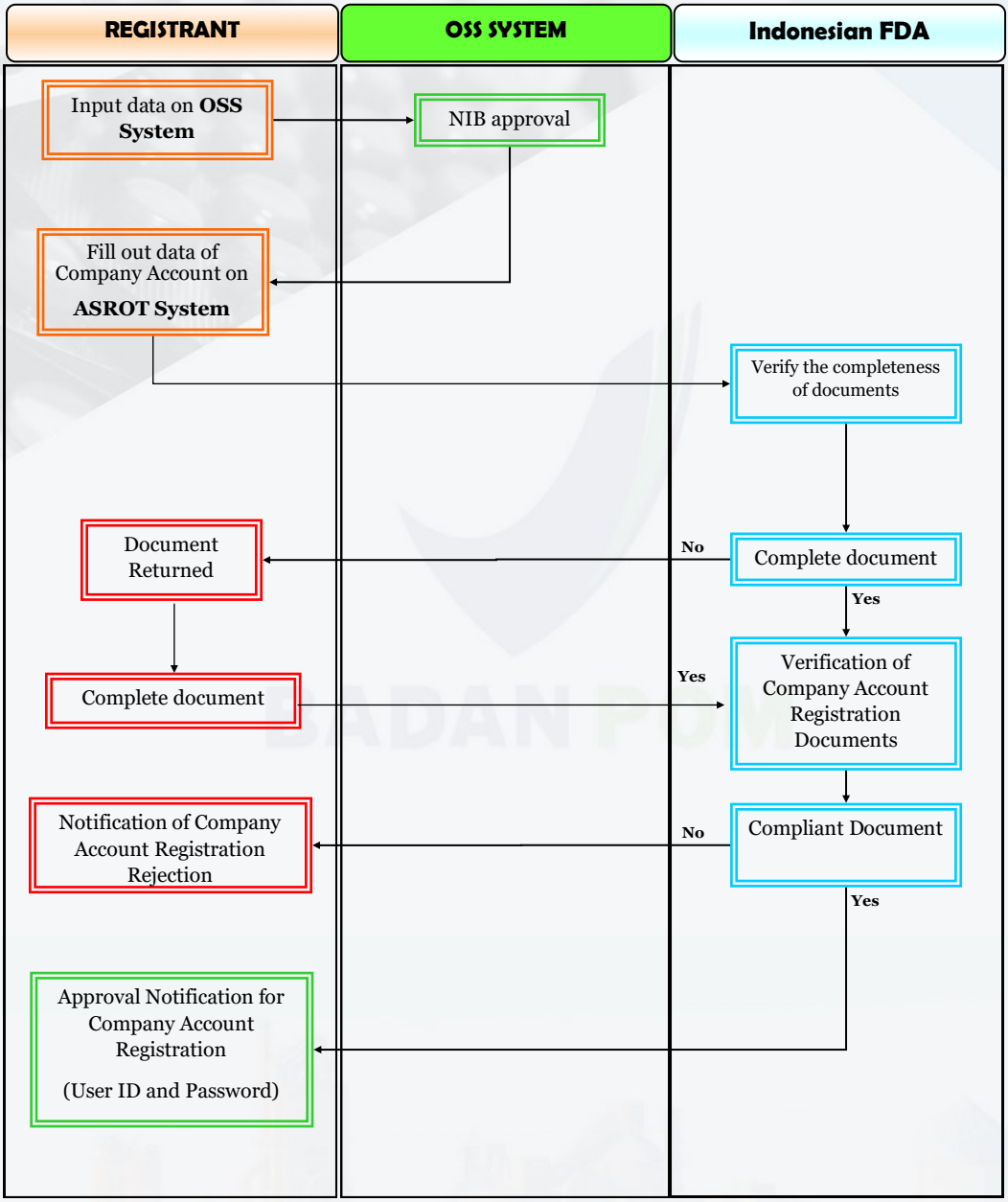
Product Registration Flow



Online Registration of Natural Medicines, Quasi Drugs and Health Supplements

https://asrot.pom.go.id/asrot

Company Account Registration



Company Account Registration

https://asrot.pom.go.id/asrot/

REQUIRED DOCUMENTS (LOCAL)

1. Business Identification Number *(Nomor Induk Berusaha, NIB)*
2. Tax Identification Number *(Nomor Pokok Wajib Pajak, NPWP)*
3. Good Manufacturing Practices certificate *(CPOB/ CPPOB/ CPOTB/ CPOTB Bertahap/ CPKB)*
4. Letter of authorization stating person in charge of company account
5. Approval Letter for manufacturing health supplements in food production facilities (for food industries registering health supplements)
6. Shared Facility Approval Letter for Pharmaceuticals and Health Supplements (for pharmaceutical industries registering health supplement)
7. Shared Facility Approval Letter for Cosmetics and Quasi Drugs (for cosmetic industries registering quasi drugs)

Company Account Registration

https://asrot.pom.go.id/asrot/

REQUIRED DOCUMENTS (IMPORT)

1. Business Identification Number (*Nomor Induk Berusaha*, NIB)
2. Tax Identification Number (*Nomor Pokok Wajib Pajak*, NPWP)
3. Letter of authorization stating person in charge of company account
4. Good Manufacturing Practice (GMP) certificate of the manufacturer from the country of origin
5. Site Master File (SMF), if the GMP certificate is for Food GMP
6. Importer Recommendation Letter issued by OSS RBA

Product Registration

In general, registration is divided into 3 types:

1. Registration of New Product

Registration of new products refers to the registration of natural medicines, quasi drugs, and health supplements that have not yet obtained marketing authorization in Indonesia.

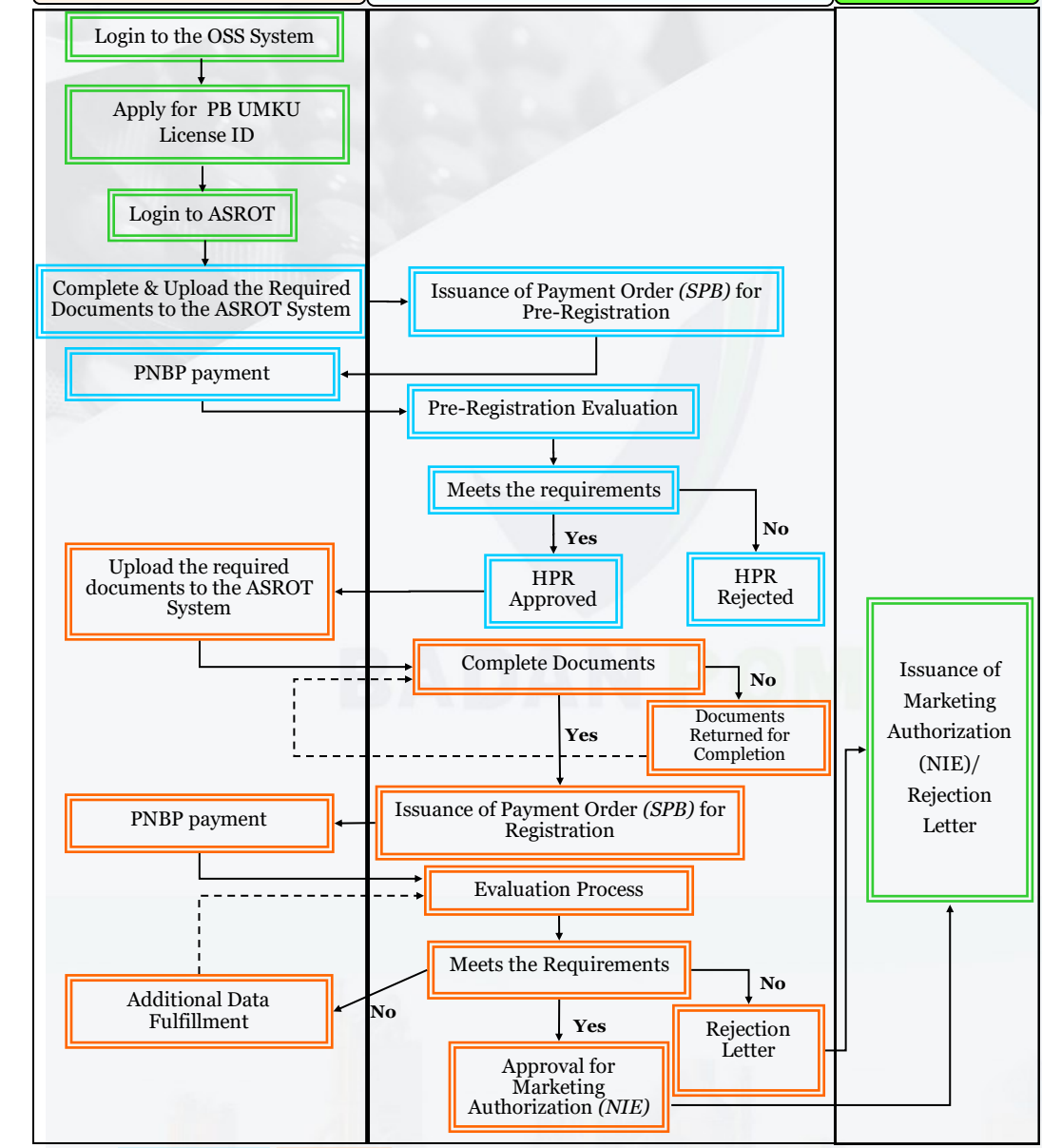
2. Renewal Registration

Renewal registration refers to the registration of natural medicines, quasi drugs, and health supplements for the extension of the validity period of their marketing authorization.

3. Variation Registration

Variation registration refers to the registration involving changes in administrative aspects, safety, efficacy, quality, and/or labeling of natural medicines, quasi drugs, and health supplements that have already been obtained marketing authorization.

Registration of New Product



Remarks : Pre-Registration | Registration

Registration of New Product

Pre-Registration Documents

Local

1. Master formula
2. Stamped Power of Attorney as Registration Officer
3. Stamped Statement Letter of Company Responsibility for Documents Authenticity
4. Contract/ Distribution/ Licensing Agreement (if applicable)

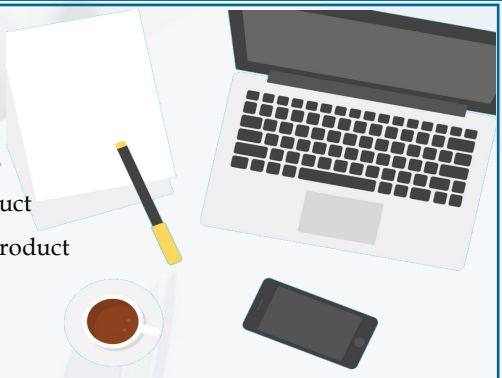
Pre-Registration Documents

Import

1. Master formula
2. Stamped Power of Attorney as Registration Officer
3. Stamped Statement Letter of Company Responsibility for Documents Authenticity
4. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP) that has been legalized by the Indonesian Embassy/ Consulate General or legalized through Apostille by the competent authority in the country of origin
5. Letter of Authorization (LoA)/ Agency Appointment Letter from the manufacturer in the country of origin.
6. Contract/ Distribution/ Licensing Agreement (if applicable)

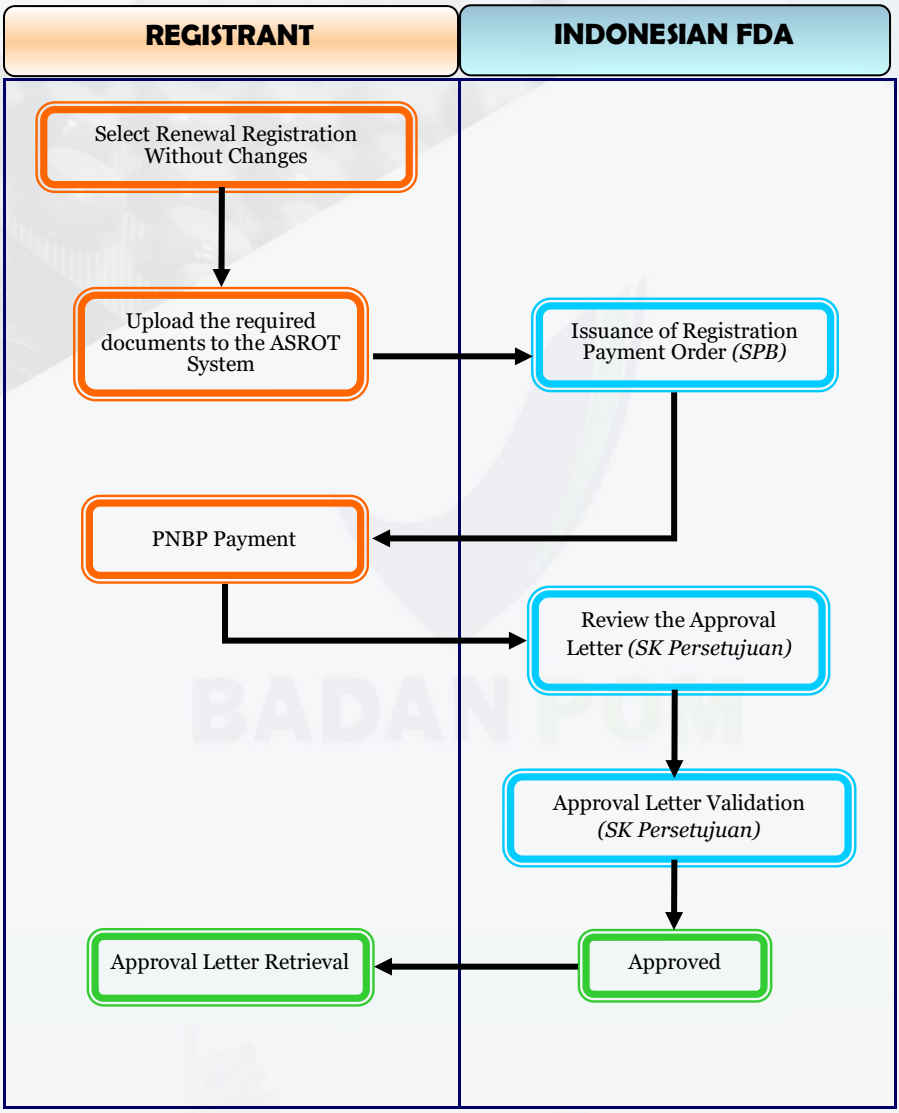
Registration of New Product

Registration Documents

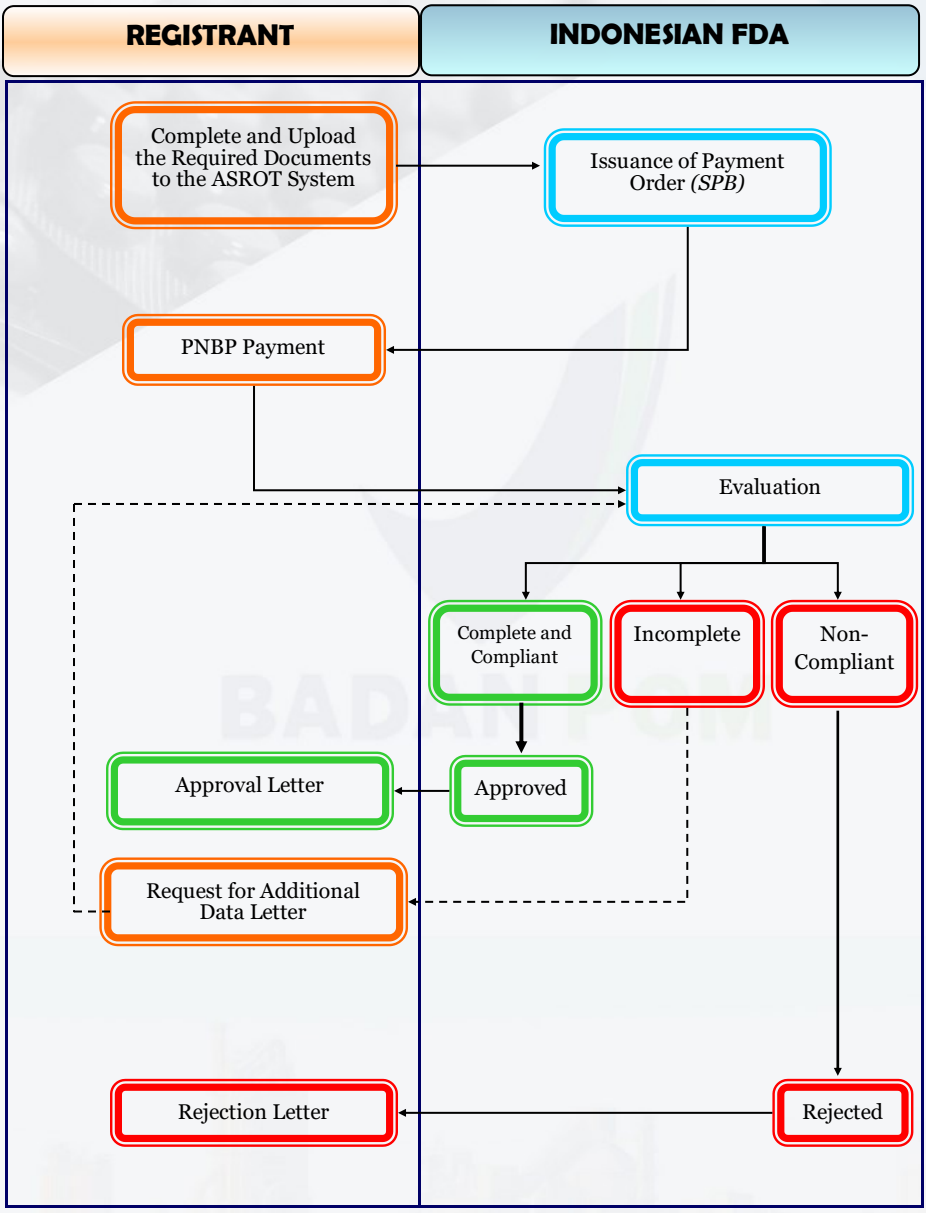


1. Product formula/composition per batch
2. Detail of product manufacturing process
3. Certificate of Analysis (CoA) of raw materials
4. Certificate of Analysis (CoA) of finished product
5. Specifications and test methods for finished product
6. Packaging specifications
7. Batch numbering system
8. Pre-Registration Results (HPR)
9. Certificate of Analysis (CoA) for capsule shell or gelatin, Bovine Spongiform Encephalopathy (BSE/ TSE) free certificate, halal certificate, and stamped statement of BSE-free capsule shell or gelatin (for capsule/ soft capsule dosage forms or gelatin raw materials, if applicable)
10. Chloramphenicol test results (for honey and its derivatives, if applicable)
11. Stability test protocol and results
12. Packaging design draft
13. Supporting data on product safety and/or efficacy (if applicable)
14. Toxicity test results (if required)
15. Origin and processing of certain materials (if applicable)
16. Halal certificate for raw materials of non-marine animal origin (if applicable)
17. Photographs of product samples from various angles **(for imported natural medicines, quasi drugs and health supplements)**
18. Safety test results from an accredited laboratory in Indonesia **(for imported products)**

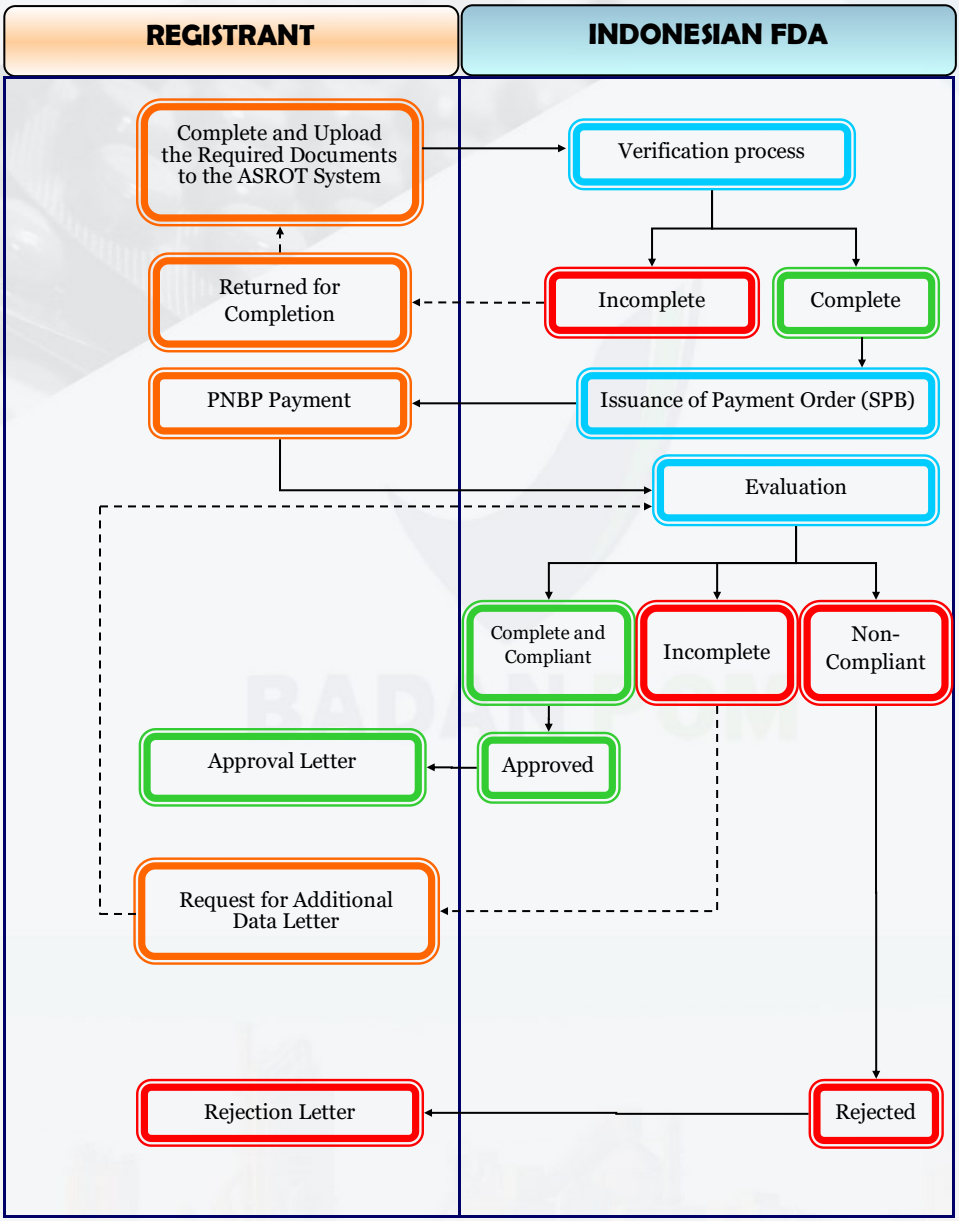
Renewal Registration Without Changes



Minor Variation Registration



Renewal Registration With Changes and Major Variation Registration



Renewal Registration

When can the renewal registration process be started?

From 180 days (D-180) to 1 day (D-1) before the expiry date of the Marketing Authorization Number.

Required Documents

Local

1. Product formula in metric units
2. Latest colored packaging design
3. Approval Letter *(SK Persetujuan)*
4. Approved packaging design
5. All previously approved variation types with packaging designs
6. Stamped statement letter confirming the product is still marketed, including the latest batch number
7. Real-time stability test results up to shelf life

Import

1. Product formula in metric units
2. Latest colored packaging design
3. Approval Letter *(SK Persetujuan)*
4. Approved packaging design
5. All previously approved variation types with packaging designs
6. Stamped statement letter confirming the product is still marketed, including the latest batch number
7. Import declaration letter
8. Latest valid Letter of Authorization
9. Real-time stability test results up to shelf life

Contract/Licensed Product

Accompanied by a valid contract/ licensing agreement

Variation Registration

MINOR VARIATION WITH NOTIFICATION

1. Change in batch numbering system
2. Change or addition of imprint, bossing, or other markings on tablets, or change/addition of printing and/or ink used on capsules
3. Change in raw material analytical method that does not alter the specifications and quality of the raw materials or finished product, and is in accordance with the pharmacopoeia monograph or other relevant references
4. Reduction of approved manufacturing sites for raw materials (active ingredients or excipients)
5. Change in name and/or address of raw material manufacturer without changing the manufacturing location
6. Change in raw material specification to comply with the latest pharmacopoeia requirements, without altering the finished product specification
7. Tightening of raw material and/or finished product specification limits.
8. Change in secondary packaging material that does not affect the printed information
9. Extension of halal logo validity period
10. Change in industrial license status without change of manufacturing site

Variation Registration

MINOR VARIATION WITH APPROVAL

1. Changes in packaging design that do not affect the safety, efficacy, and/or quality of the natural medicine/ health supplement/ quasi drugs, and do not alter the information approved in the Marketing Authorization, including:
   - Change in packaging design color
   - Change in layout of images and/or product information
   - Change in font type or size
   - Addition or modification of company logo
   - Addition or modification of halal logo
   - Removal of foreign language from labeling
   - Change in packaging shape and/or dimensions without change in primary packaging material specifications
2. Change of product name
3. Change of product image
4. Addition of logo/trademark
5. Addition of award logo or other logos
6. Addition of product information in English or other languages
7. Change of tagline that does not affect product efficacy or intended use
8. Inclusion of distributor information
9. Change of information presented on packaging design
10. Change or addition of brochure/leaflet
11. Change or addition of secondary packaging
12. Change or addition of packaging size/pack size
13. Change in name and/or address of the registrant, licensor, and/or manufacturer without change of location (and without change in ownership status)
14. Change in name and/or address of the applicant company (office), licensor, or importer with change of location (without change in ownership status)
15. Change or addition of secondary packaging manufacturer
16. Application for special or promotional packaging
17. Change in capsule shell color (for NM & HS)
18. Change in finished product specification to comply with current compendial or regulatory requirements
19. Change in analytical method for raw materials (non-compendial) that does not alter the specifications of the raw material or finished product
20. Reduction or elimination of active ingredient overage
21. Increase or decrease in batch size up to ten-fold, provided reproducibility and finished product specifications remain unchanged
22. Change or addition of capsule shell manufacturer that does not alter capsule shell specifications (for NM & HS)
23. Change in capsule shell size (for immediate-release capsules) that does not affect formulation, product specifications, or stability (for NM & HS)
24. Change in tablet shape or dimensions (for immediate-release tablets) that does not alter formulation, average weight, or product specifications (except dimensions)
25. Change in analytical method for finished product that does not alter product specifications
26. Change in product storage conditions
27. Change and/or addition of active ingredient manufacturer that does not alter raw material or finished product specifications
28. Change or addition of export destination country
29. Change and/or addition of excipient manufacturer that does not alter raw material or finished product specifications

Variation Registration

MAJOR VARIATION

1. Change in finished product specifications
2. Change in product formula that does not affect the safety or efficacy of the product
3. Change in product claims, tagline, and/or directions for use
4. Change in type or specification of primary packaging material
5. Change in stability data (update or revision based on new study results)
6. Change or addition of manufacturing and/or primary packaging site
7. Change in raw material specifications
8. Increase in batch size of more than tenfold, provided reproducibility and finished product specifications are maintained
9. Change in manufacturing process that does not alter the product formulation or finished product specifications

Variation Registration

Required Documents

The requirements for variations depend on the type of variation submitted. However, in general, the requested documents include:

1. Approval Letter (SK Persetujuan)
2. All previously approved variation types along with packaging designs
3. Approved packaging design
4. New packaging design being proposed
5. Comparison matrix of the proposed changes
6. Documents referring to the type of variation submitted

Example: If applying for the inclusion of a halal logo, a valid halal certificate is required.

LIST OF ABBREVIATIONS

ASROT	: e-Registration System Application for Natural Medicines, Quasi Drugs and Health Supplements
BSE	: Bovine Spongiform Encephalopathy
CFS	: Certificate of Free Sale
CoA	: Certificate of Analysis
CPKB	: *Cara Pembuatan Kosmetika yang Baik*
CPOB	: *Cara Pembuatan Obat yang Baik*
CPOTB	: *Cara Pembuatan Obat Tradisional yang Baik*
CPPOB	: *Cara Produksi Pangan Olahan yang Baik*
CPP	: Certificate of Pharmaceutical Products
GMP	: Good Manufacturing Practice
HPR	: *Hasil Pra Registrasi*
LoA	: Letter of Authorization
NIB	: *Nomor Induk Berusaha*
NIE	: *Nomor Izin Edar* (Marketing Authorization Number)
NPWP	*: Nomor Pokok Wajib Pajak*
OBA/ NM	: *Obat Bahan Alam* (Natural Medicines)
OK/ QD	: *Obat Kuasi* (Quasi Drugs)
OSS-RBA	: Online Single Submission Risk-Based Approach
PNBP	: *Penerimaan Negara Bukan Pajak*
PP	: *Peraturan Pemerintah*
SK/ HS	: *Suplemen Kesehatan* (Health Supplements)
SMF	: Site Master File
SPB	: *Surat Perintah Bayar (*Payment Order)
TSE	: Trasmissible Spongiform Encephalopathy
WIB	: Western Indonesia Time

Consultation Service

Athena Building, 5th Floor
Directorate of Traditional Medicines, Health Supplements, and Cosmetics Registration — Indonesian Food and Drug Authority
Jl. Percetakan Negara No. 23, Jakarta Pusat 10560

1. Customer Service (CS)

In-Person Consultation : Monday to Thursday, 08.30—15.00 WIB

Online (via Live Chat) : Monday and Wednesday, 08.30—15.00 WIB

OBA, OK & SK: via the "Chat ASROT" menu; Advertisement: via "Konsultasi Online" menu in SIREKA

2. Duty Manager (DM) Consultation

In-Person Consultation : Advertisement (Monday), OBA Product (Tuesday), OK and SK Products (Thursday), 08.30—15.00 WIB

3. IT Consultation

In-Person Consultation : Monday and Wednesday, 08.30—15.00 WIB

Online (via Whatsapp) : Tuesday & Thursday, 08.30—15.00 WIB

4. Priority Service Counter

In-Person Consultation : Monday to Thursday, 08.30—15.00 WIB

For pregnant women, elderly, and persons with disabilities

5. Product Registration Status Follow-Up

WhatssApp (0811 2333 669): Monday to Thursday, 08.30—15.00 WIB

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iklan_otsk@yahoo.com (Advertisement)

WA for Advertisement Consultation:
0857-6554-6186

WA for IT Consultation:
0811-9690-6095

IT Email :
it_regotskkos@pom.go.id

E-Registration System : **https://asrot.pom.go.id/asrot/**

Download Regulatory Documents : **https://jdih.pom.go.id**

Subsite: **https://registrasiotskk.pom.go.id**

The registration fee is in accordance with *PP No. 32 Tahun 2017 Tentang Jenis dan Tarif Atas Jenis PNBP yang Berlaku Pada Badan Pengawas Obat dan Makanan*