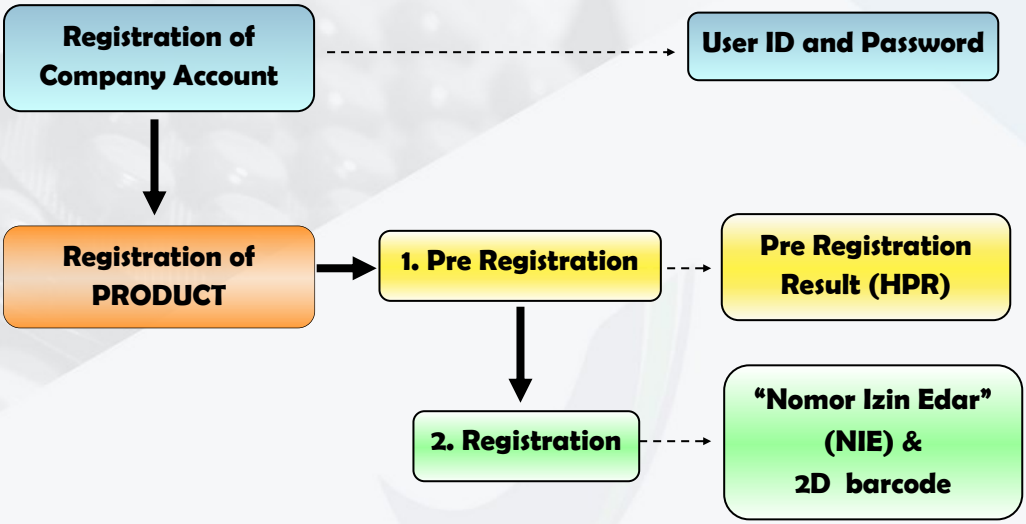
INDONESIAN FDA

GUIDANCE BOOK OF TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT REGISTRATION

DIRECTORATE OF TRADITIONAL MEDICINES, HEALTH SUPPLEMENT, & COSMETIC REGISTRATION

INDONESIAN FOOD AND DRUG AUTHORITY (INDONESIAN FDA)

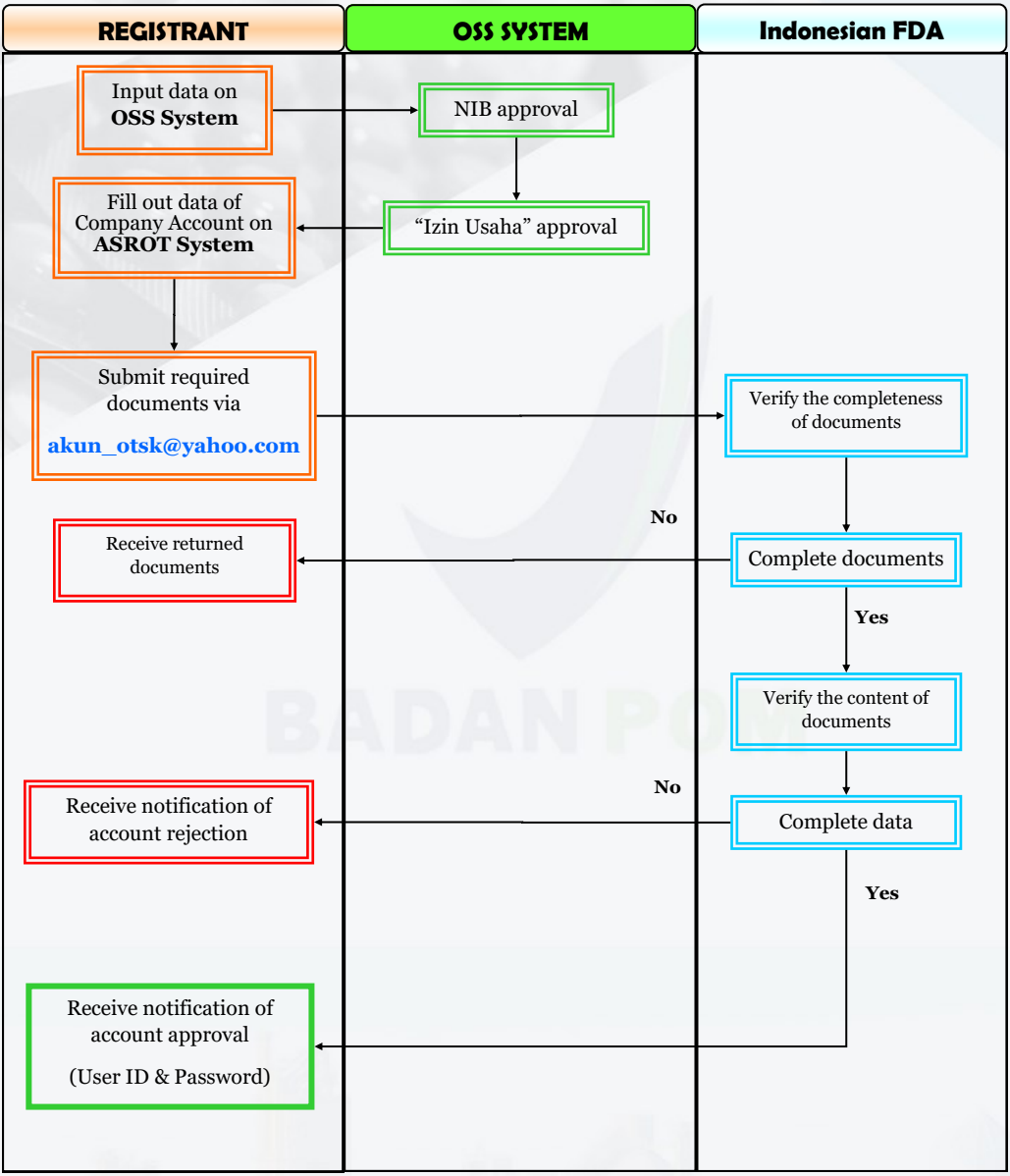
Product Registration Flow



Online registration of traditional medicine and health supplement product

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

Registration of Company Account



Registration of Company Account

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

DOCUMENT REQUIREMENTS (LOCAL)

1. Single Business Number (*Nomor Induk Berusaha*, NIB)
2. Individual Tax Number (*Nomor Pokok Wajib Pajak*, NPWP)
3. Production License
4. Certificate of CPOB / CPOTB / CPPOB / Certificate of partial CPOTB
5. Letter of authorization stating person in charge of company account

DOCUMENT REQUIREMENTS (IMPORTER)

1. Single Business Number (*Nomor Induk Berusaha*, NIB)
2. Individual Tax Number (*Nomor Pokok Wajib Pajak*, NPWP)
3. Business License / *Surat Izin Usaha Perdagangan* (SIUP)
4. Certificate of Good Manufacturing Practice (GMP) of manufacturer from country of origin
5. Letter of authorization stating person in charge of company account

Product Registration

Divided into 4 types :

1. Registration of New Product

Registration of new product is registration of traditional medicine, health supplement, and quasi product which do not have registration number (*Nomor Izin Edar*, NIE) in Indonesia yet.

2. Renewal Registration

Renewal registration is registration to extend the validity period of registration number (*Nomor Izin Edar*, NIE).

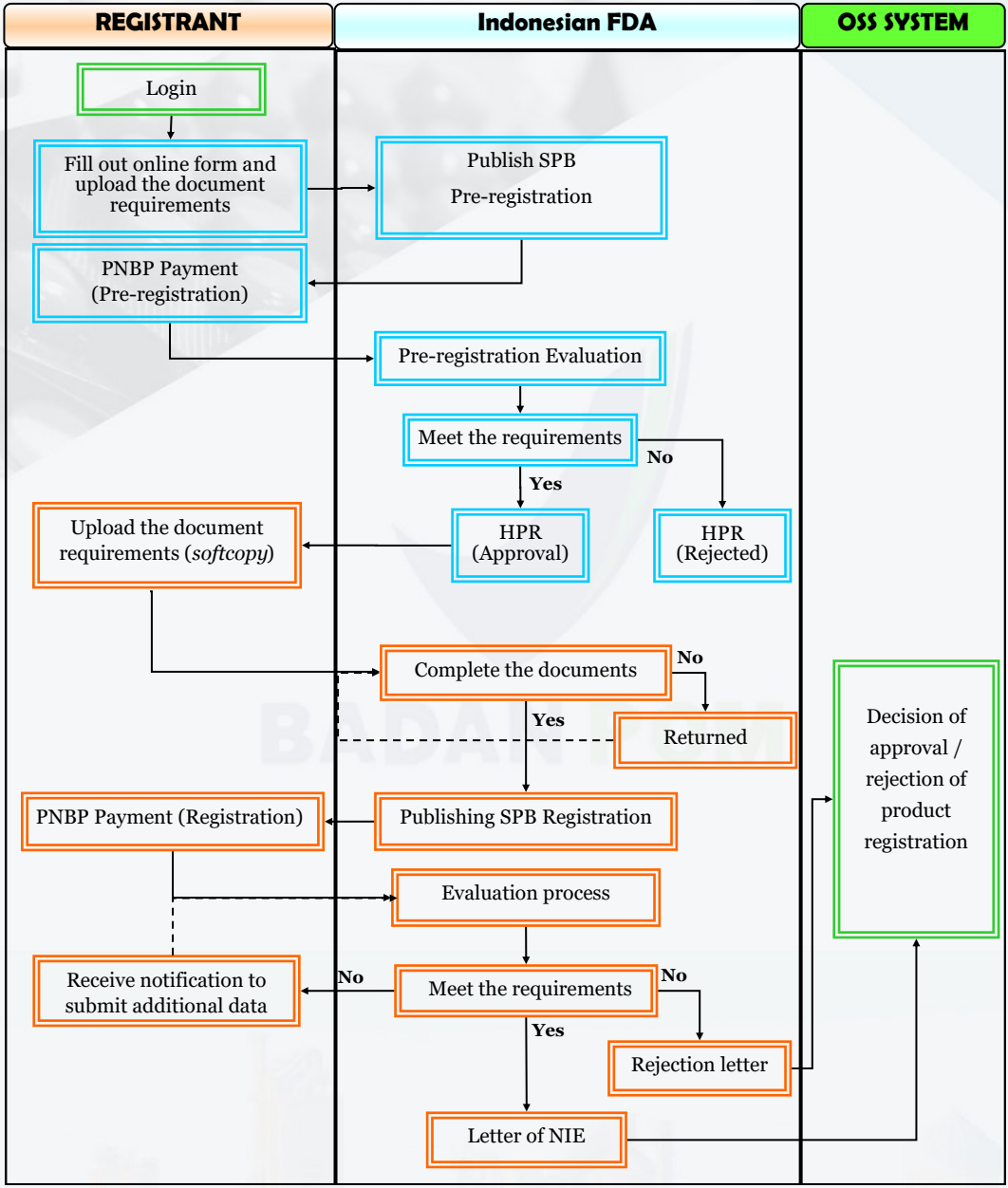
3. Registration of Product Variation

Registration of product variation is registration of administrative and/or technical data variation in traditional medicine, health supplement, and quasi product which already have registration number (*Nomor Izin Edar*, NIE).

4**. Registration for Export**

Registration for Export is registration for traditional medicine, health supplement, and quasi product which are intended specifically to be exported.

Registration of New Product



Registration of New Product

DOCUMENTS FOR PRE-REGISTRATION

Local

Upload

1. Master formula
2. Letter of authorization for person in charge of product registration
3. Statement letter of company responsibility for document authenticity
4. Cooperation Agreement on Contract Manufacturing/ Distribution/ Licensing (if any)

DOCUMENTS FOR PRE-REGISTRATION

Importer

Upload

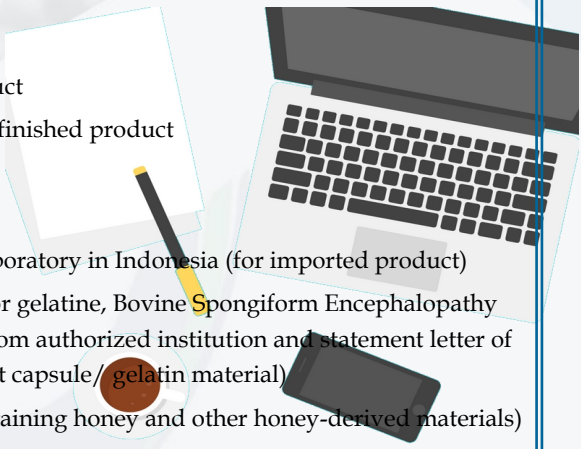
1. Master formula
2. Letter of authorization for person in charge of product registration
3. Statement letter of company responsibility for document authenticity
4. CFS/ CPP issued by authorized government agency in the country of origin and legalized by Indonesian Consulate General or Indonesian Embassy
5. LoA/ Letter of authorization for distribution from industry in the country of origin

Registration of New Product

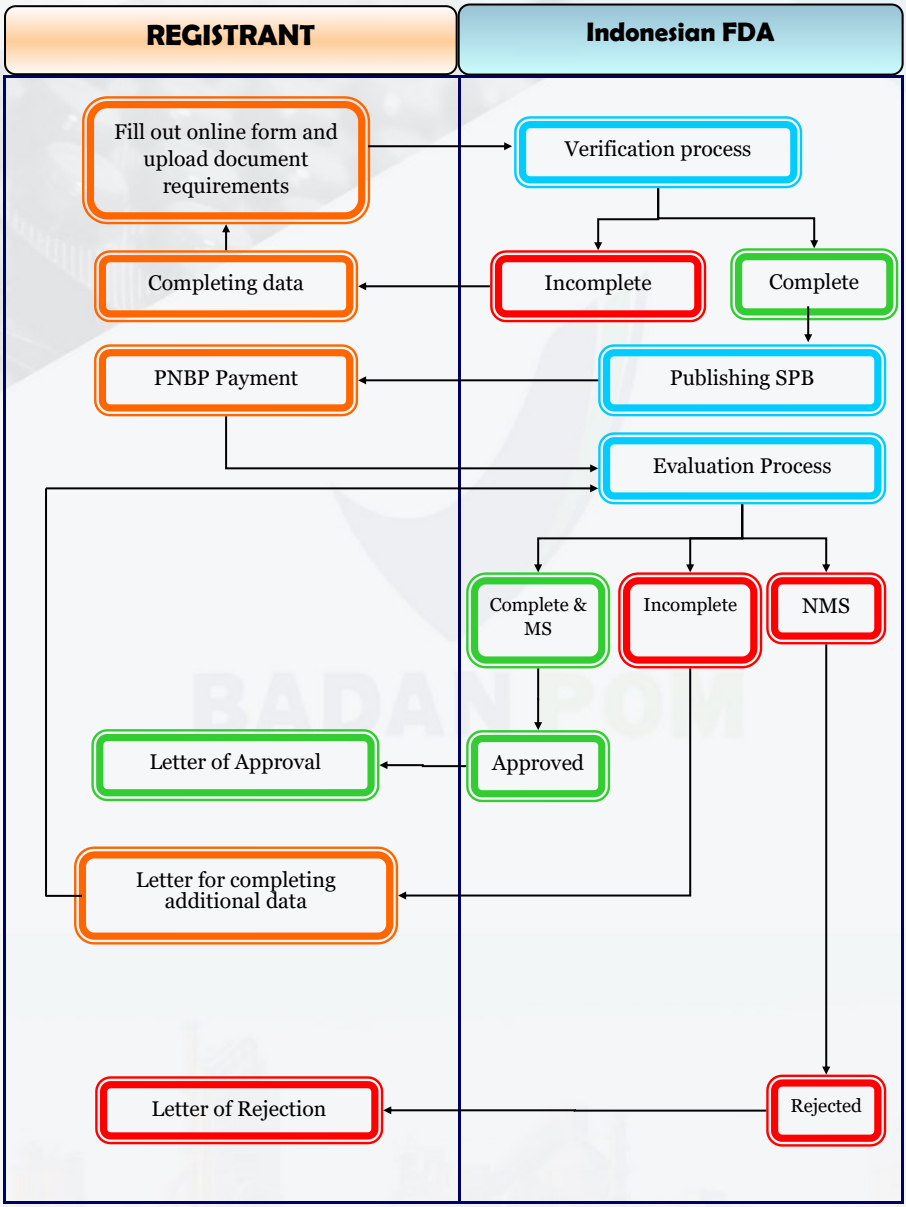
REGISTRATION Documents

Upload

1. Product composition (per batch)
2. Detail of manufacturing process
3. Certificate of analysis of raw material
4. Certificate of analysis of finished product
5. Specification and analytical method of finished product
6. Specification of packaging material
7. Batch numbering system
8. Safety test result from an accredited laboratory in Indonesia (for imported product)
9. Certificate of analysis of capsule shell or gelatine, Bovine Spongiform Encephalopathy (BSE) free certificate, halal certificate from authorized institution and statement letter of BSE free capsule (for hard capsule/ soft capsule/ gelatin material)
10. Chloramphenicol test (for product containing honey and other honey-derived materials)
11. Protocol and result of stability test
12. Packaging design
13. Supporting data regarding Safety and Efficacy
14. Toxicity test result (if required)
15. Origin and gaining process of certain material (if any)
16. Halal certificate for raw material from non marine origin (if any)
17. Picture of original packaging from each angle (for imported traditional medicine, local & imported health supplement, and local & imported quasi drug)
18. Certificate of Free Sale (imported product only)



Renewal Registration, Registration of Product Variation, and Registration for Export Flow



Renewal Registration

When does registrant start to do renewal registration process ?

D-180 until D-1 before expiration of NIE (registration number)

Document Requirements

Local

1. Formula in metric unit
2. Newest full colour packaging design
3. Approval letter
4. The last packaging design which has been previously approved
5. All variations and packaging desaign which have been previously approved
6. Letter of declaration stating the product are still freely marketed along with the last batch number
7. Result of stability test for health supplement (periodically until expiration date)

Import

1. Formula in metric unit
2. Newest full colour packaging design
3. Approval letter
4. The last packaging design which has been previously approved
5. All variations and packaging desaign which have been previously approved
6. Letter of Declaration stating the product are still freely marketed along with the last batch number
7. Certificate of Imported Product (*Surat Keterangan Impor*, SKI)
8. Letter of Authorization / Appointment (LoA)
9. Result of stability test for health supplement (periodically until expiration date)

Toll Manufacturing/ Licensed Product

Newest toll manufacturing / license agreement

Registration of Product Variation

1. Changes of packaging design, such as but not limited to:
   - colour of packaging design
   - images or product information layout
   - type or size of the writing
   - company logo
   - halal logo
   - removal of foreign language
   - shape and/or dimension of packaging without changes in specification and size of packaging
2. Changes of batch numbering system
3. Changes or addition of imprint bossing or other marking on tablet; changes or addition of printing and/or ink on capsule
4. Changes of analytical method for raw material and/or finished good which do not change specification and quality of the raw material and/or finished good
5. Changes or addition of raw material manufacturer which do not alter specification and quality of raw material and/or finished good
6. Changes of batch size
7. Changes of finished good specification for adjusting with latest compendial or latest regukation

Minor Variation by Notification

Registration of Product Variation

Minor Variation by Approval

1. Changes of product name
2. Changes of packaging design, such as but not limited to images, non-company logo, addition of product information in English or other languages, tag line which does not affect product efficacy, inclusion of distributor, and changes of information
3. Changes or addition of secondary packaging and/or brosur/leaflet
4. Changes or addition of packaging size
5. Changes of name/addreses of registrant, manufacturer, and/or license provider without location change
6. Changes of name/addreses of registrant (office), importer, or license provider with location change (without change of ownership status)
7. Changes or addition secondary packaging factory
8. Special package request
9. Changes of raw material specification or manufacturing process which do not change the quality and stability of finished good
10. Changes of stability related to reduction of expiration date
11. Extension request for finishing product stock with old packaging
12. Changes of production technology
13. Changes of capsule-shell's colour

Major Variation

1. Changes of raw material and/or finished good specification
2. Changes of product composition which do not affect product safety and efficacy
3. Changes of efficacy claim and/or posology which affects efficacy
4. Changes of type and specification of primary packaging material
5. Changes of product stability regarding extension of expiration date
6. Changes or addition of production location and/or primary packaging location
7. Changes of registrant name along with changes of ownership status
8. Changes of product status (imported to local, licensed to local, and imported to licensed)
9. Changes of importer
10. Changes of manufacturing license without changes on manufacturer location

Registration of Product Variation

DOCUMENT REQUIREMENTS

The requirements for registration of product variation depend on the type of variation proposed.

1. Approval Letter
2. All variations which have been previously approved
3. The last packaging design which has been previously approved
4. Newest full colour packaging design
5. The information about data change
6. The supporting document for type of variation proposed

For example :

If there is a submission for adding halal logo at packaging design, a valid halal certificate is required.

Registration for Export

Registration for Export is divided into 2 types:

1. **Registration for Export (Existing)** is reserved for export product which have been registered on Indonesian FDA
2. **Registration for Export (New)** is reserved for export product which have not registered yet on Indonesian FDA (export-only)

Document Requirements

Export (Existing)

1. Approval letter
2. Packaging design which has been previously approved
3. Letter of Declaration stating exporting country
4. Packaging Design for Export
5. Variations and packaging desaign which have been previously approved

Export (New)

1. Master Formula
2. Certificate of Analysis of finished product
3. Letter of Declaration stating exporting country
4. Packaging Design for Export

LIST OF ABBREVIATIONS

ASROT	: Aplikasi Sistem e-Registrasi Obat Tradisional dan Suplemen Kesehatan
BSE	: Bovine Spongiform Encephalopathy
CFS	: Certificate of Free Sale
CoA	: Certificate of Analysis
CPP	: Certificate of Pharmaceutical Products
CPOB	: Cara Pembuatan Obat yang Baik
CPOTB	: Cara Pembuatan Obat Tradisional yang Baik
CPPOB	: Cara Produksi Pangan Olahan yang Baik
GMP	: Good Manufacturing Practice
KBRI	: Kedutaan Besar Republik Indonesia
Konjen	: Konsulat Jenderal
MS	: Memenuhi Syarat
NIB	: Nomor Induk Berusaha
NIE	: Nomor Izin Edar
NPWP	: Nomor Pokok Wajib Pajak
OSS	: Online Single Submission
PNBP	: Penerimaan Negara Bukan Pajak
Prareg	: Pra Registrasi
Reg	: Registrasi
SIUP	: Surat Izin Usaha Perdagangan
SKI	: Surat Keterangan Impor
SPB	: Surat Perintah Bayar
TMS	: Tidak Memenuhi Syarat

PRODUCT REGISTRATION SERVICE

Public Service Building (Building B), 2nd Floor

Directorate of Traditional Medicines, Health Supplement & Cosmetic Registration

Indonesian Food and Drug Authority (Indonesian FDA)

Jl. Percetakan Negara No. 23, Jakarta Pusat 10560

1. **Duty Manager Consultation**
   Monday - Friday 08.30 - 16.00
   - Live Chat via ASROT
   - Whatsapp and Phone: +62-811-2333-669
   - Via Zoom (Only on Monday, by Appointment)
   - Via Email:
     *) penilaian_ot@pom.go.id
     (for Traditional Medicine)
     *) penilaian_sm_kuasi@pom.go.id
     (for Health Supplement & Quasi Product)

2. **IT Consultation**
   Monday - Friday 08.30 - 16.00
   Whatsapp: +62-811-9690-6095

3. **Mailing**
   - Via Email: ditlai_otsmkos@yahoo.co.id
   - Hardcopy Mail:
   Directorate of Traditional Medicines, Health Supplement & Cosmetic Registration
   Building F Barat, 2nd floor, Indonesian FDA
   Jl. Percetakan Negara No. 23, Jakarta Pusat 10560

E-registration website : **https://asrot.pom.go.id/asrot/**

Download the regulations : **https://jdih.pom.go.id**

In accordance to PP 32 Tahun 2017 Tentang Jenis dan Tarif Atas Jenis PNBP yang Berlaku Pada Badan Pengawas Obat dan Makanan