7th Club

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Club Founder
Dr. Mahmoud Bahgat

Regulatory Affairs Club

Food supplement registration in KSA
تسجيل المكملات الغذائية فى السعودية

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Co-Founder & Host:
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Online Zoom
7 pm Egypt - 7 pm KSA - 8 pm UAE

Registration of Food Supplements with SFDA

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Outlines

1. Introduction to SFDA Food Registration
2. Food Supplements Definition & Scope
3. Registration Process Overview
4. Financial Requirements
5. Technical Requirements & Documentation
6. General Controls & Compliance
7. Common Errors to Avoid
8. Q&A Session

Learning Objectives

- Understand SFDA food supplement registration requirements
- Identify required documentation and fees
- Avoid common registration mistakes
- Comply with technical regulations

Introduction (1/2)

- The Saudi Food and Drug Authority (SFDA) plays a crucial role in safeguarding public health in Saudi Arabia by regulating food, drugs, medical devices, and cosmetics.

- A key aspect of their work involves rigorous evaluation and registration processes.

Introduction (2/2)

- For instance, any company wishing to market food supplements in KSA must navigate the complex Food supplements registration process, adhering to strict quality and safety standards set by the SFDA.

- Food supplements need SFDA approval to be legally marketed and sold in Saudi Arabia.

Food Supplements Definition & Scope (1/3)

- *Products intended to supplement the normal diet containing single or multiple ingredients with nutritional or physiological effects.*

Food Supplements Definition & Scope (2/3)

- **Available Forms:** Oral consumption supplements;
  - Chewable tablets
  - Effervescent tablets
  - Tablets & Pills
  - Capsules
  - Gummies
  - Candies
  - Lozenges
  - Drops
  - Liquids
  - Ampoules
  - Powders
  - Sprays

Food Supplements Definition & Scope (3/3)

Permitted Components:

- Bovine colostrum
- Plants/herbs & extracts
- Fibers
- bee products: (Royal jelly, propolis, pollen - with allergy warnings)
- Melatonin
- Vitamins & Minerals
- Probiotics & Prebiotics
- Fatty acids & amino acids
- Collagen
- Enzymes & Co-Q10

Registration Process Overview (1/7)

- **SFDA registration pathways for food supplements:**

A. Special food in the Food Sector of SFDA:

✓ If ingredients, claims, dosage forms, & other labelling information are as per SFDA requirements for food supplements

Registration Process Overview (2/7)

- **SFDA registration pathways for food supplements:**

B. Health/herbal products in the Drug Sector:

- ✓ if ingredient concentration exceeding the daily limit or has a non-accepted food claim
- ✓ requires a CTD or eCTD file, as per ICH guidelines, similar to the requirements for drug registration.
- ✓ the SFDA will conduct a GMP inspection of the manufacturer

❖ **Examples include** Vitamin D 5,000 IU, sexual health products, and all other herbal products with therapeutic effects.

Registration Process Overview (3/7)

- **SFDA registration pathways for food supplements:**

➢ Supplement registration through the special food application is generally more straightforward.

➢ However, it is still tricky; inexperienced applicants might waste fees and months in the wrong direction.

Registration Process Overview (4/7)

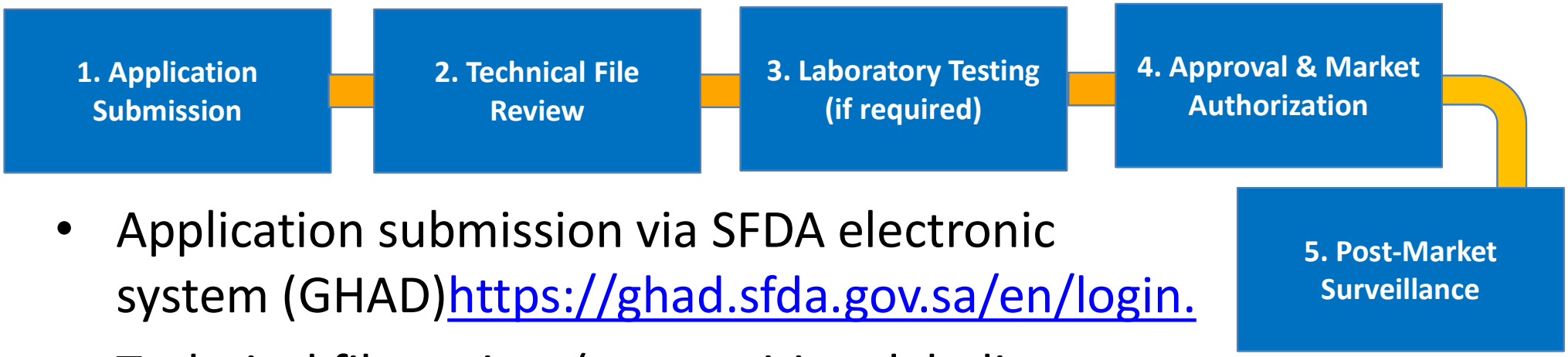
- **SFDA registration pathways for food supplements:**

➢ **If the product is unclear,** an expert must review the procedure under which it should be registered.

➢ Alternatively, the applicants can apply for SFDA classification before they apply for registration.

Registration Process Overview (5/7)

Registration Pathway:



- Application submission via SFDA electronic system (GHAD)https://ghad.sfda.gov.sa/en/login.
- Technical file review (composition, labeling, safety).
- Laboratory testing (if required).
- Approval & Market Authorization by SFDA.
- Post-market surveillance obligations.

Registration Process Overview (6/7)

Registration Timeline:

- **60 Working days**

📊 *Duration calculated from electronic submission date*

⚠️ **Remember:** Registration ≠ License (No certificate issued)

Registration Process Overview (7/7)

- **Response Timeline & Follow-up:**

⏰ **Important Deadlines:**

  - **Client Response Time: 30 days maximum**
    - To address SFDA comments
    - To provide additional information
    - To correct deficiencies

⚠️ **Consequences of Delays:**

- Application termination
- Need to resubmit new application
- Fees non-refundable

Financial Requirements

- 💰 **Registration Fees:**
  - **Main Product:** 5,000 SAR
  - **Additional Sizes/Weights:** 500 SAR each

- 💰 **Renewal Fees:**

  - 2,000 SAR

Technical Requirements & Documentation (1/7)

- **Key Requirements:**
  1. Ingredients must comply with approved SFDA lists
  2. Levels of vitamins & minerals must remain within permitted ranges
  3. Health claims must comply with relevant technical regulations
  4. Additives & residue limits must meet SFDA approved specifications
  5. Labeling information must meet SFDA labeling requirements

Technical Requirements & Documentation (2/7)

Essential Documentation Checklist:

1. **Product label layout** (complete artwork from all sides)
2. **Certificate of Composition**
3. **Technical Data Sheet (TDS):** Required in mg/kg units - Based on SFDA.FD/GSO 2500 regulation - Must include all active ingredients - Specify non-active ingredients
4. **Final product image** (3D images showing packaging type)

Technical Requirements & Documentation (3/7)

- **Additional/Optional Requirements (Available Upon Request if applicable):**

  - Free Sale Certificate (imported products)
  - Halal certificate
  - HACCP/GMP/ISO 22000 certificates
  - Stability study (self-life
  - Safety testing (heavy metals, pesticides, pathogens)

Technical Requirements & Documentation (4/7)

- **Additional Requirements:**

➢ 🌿 **For Products Containing Herbs/Extracts:**

- ❑ Scientific name and family classification
- ❑ Traditional/common name
- ❑ Plant part used
- ❑ Quantity used in product
- ❑ Purpose of use
- ❑ International safety studies

Technical Requirements & Documentation (5/7)

Labeling Requirements:

- Must be in Arabic (mandatory).
- **Product name**: must state “Food Supplement” followed by main component.
- **Nutritional Information:** - Nutritional data per 100g/ml and per serving - Active ingredient quantities in specified units - Energy content in calories

Technical Requirements & Documentation (6/7)

Labeling Requirements:

- **Additional Requirements:** - Net weight/quantity indication - Production and expiry dates - Storage conditions before and after opening - Purpose of use for high-dose nutrients - Reference number (P-3-N-000000-0000)

- ❌ **Prohibited:** - SFDA logo or endorsement claims - Unlicensed health claims

Technical Requirements & Documentation (7/7)

Warnings & Precautions:

- Special warnings for high doses of iron, zinc, vitamin A, vitamin E, chromium, selenium, potassium, magnesium.
- Pregnant & breastfeeding women: consult medical advice.
- Patients with chronic diseases must seek medical advice before use.
- Warnings & disclaimers: not exceed daily dose, keep out of children's reach, not substitute for diet.

Common Mistakes to Avoid

❌ **Top Registration Errors:**

1. **Incomplete documentation** - Missing TDS or certificates
2. **Incorrect labeling** - Wrong warnings or claims
3. **Payment issues** - Incorrect fee amount or service type
4. **Data inconsistencies** - Mismatched product information
5. **Regulatory non-compliance** - Exceeding permitted limits
6. **Timeline violations** - Late responses to SFDA queries

Conclusion (1/2)

Key Takeaways:

- SFDA registration ensures safe, effective, and properly labeled supplements.
- Compliance with composition, packaging, labeling, and storage is mandatory.
- Continuous monitoring & adherence protects public health.
- Licensed warehouse required for import and storage

Conclusion (2/2)

Key Takeaways:

- ***For Manufacturers:***

✓ Ensure all ingredients are from approved lists

✓ Comply with dosage limits and labeling requirements

✓ Include mandatory warnings and statements

✓ Maintain quality within tolerance limits

References

- 📚 **Key Regulations to Follow:**

Regulation	Code
SFDA.FD 55	Food Supplements
GSO 9	Food Labeling
SFDA.FD 150-1/2	Shelf Life
SFDA.FD 2500	Food Additives
SFDA.FD 2333	Health Claims


ANSWER
QUESTION

Need Support?

- **Presenter Contact:**

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- **Contact us to request a proposal or meet with our experts**

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THANK
YOU!