Fmhaca Guidelines

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Fmhaca Guidelines

The Ethiopian Food and Drug Administration (EFDA) is mandated, in the proclamation 661/2009, to ensure the safety, quality and efficacy of medicines. To achieve this, the authority has been working on different regulatory activities. The medicine market authorization system is one of the top priority areas that have been implemented.

EFDA – Ethiopian Food and Drug Administration

Guideline for Registration of Medical devices 2014. The Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia was established to safeguard the health and safety of patients, users, and other persons by ensuring that manufacturers of medical devices follow specified procedures during the design, manufacture, and marketing as described in Proclamation No. 661/2009 for the regulation of medicines and….

Medical Device Guidelines – EFDA

Guideline for Registration of Medical devices 2014: The Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia was established to safeguard the health and safety of patients, users, and other persons by ensuring that manufacturers of medical devices follow … February 26, 2019

Publications – EFDA

The document is adapted from Guidance Document Harmonized Requirements for the Licensing of Vaccines and Guidelines for the Preparation of an Application, Health Canada, 2016 and is based on the requirements of the International Conference on Harmonization (ICH) Common Technical Document (CTD) and the Technical Report Series of the World Health Organization.

Food, Medicine and Healthcare Administration and Control ...

This Guideline is intended to provide guidance to the applicants on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant deoxyribonucleic acid (DNA) technology (rDNA-derived biotherapeutics) and intended for use in humans.

Food, Medicine and Healthcare ... - fmhaca.gov.et

FMHACA is responsible to ensure the quality, safety and/or efficacy of medicines, food, cosmetics and medical devices. It sets standards for health and health related institutions, healthcare practice, competence and ethics of health professionals.

Food, Medicine and Health Care Administration and Control ...

This Guideline succeeds and supersedes the 2008 Guideline, which was in use for drug approval and registration. It is prepared with the same purpose: to inform manufacturers of what documentation should be submitted with requests for approval and registration of pharmaceutical products. The Guideline provide recommendations on the quality, safety and efficacy information for both active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP) that should be submitted to ...

Guideline for Registration of Medicines 2014 – EFDA

Products approved by FMHACA based on the recommendation of the dossier assessor team , the laboratory quality assessment and the clinical review advisory committee a registration number

and a market authorization certificate will be given to the product and the applicant respectively. The product is then entered into the Medicines Register.

eRIS - Electronic Regulatory Information System
The tool was developed based on WHO guideline and contains detail description on the general content of the medicine legislation and a checklist for the functions of the medicine regulatory authority as evaluation points. The basic purpose for record/archival review was to assess the comprehensiveness of the legal framework to protect public ...

Pharmaceutical Regulatory Framework in Ethiopia: A ...
Welcome to Electronic Regulatory Information System (eRIS) of EFDA iRegister iRegister is an online application which allows importers to apply for and receive medicine registration certificate to import medicines online and FMHACA staff to manage these applications online.

eRIS - Electronic Regulatory Information System
Details: Prior to and after placing the product on the market, the manufacturer should put a process in place, as part of its quality management system, to assess the continued conformity of the device to the essential principles of safety and performance through the post-marketing phase. Guideline (Sept. 2014), Section II, Art. 2.2

Ethiopia
The Federal Food, Drug and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301). A cosmetic may...

Good Manufacturing Practice (GMP) Guidelines/Inspection ...
For HIV Screening and related guidelines, the ACP recommends the Centers for Disease Control and Prevention (CDC). Requests for bulk reprints (minimum, 100 copies) of all guidelines published in Annals of Internal Medicine may be made to Aileen McHugh, via phone at 215-351-2642 or via email at reprints@acponline.org .

Clinical Practice Guidelines and Recommendations | ACP
Food, Medicine and Health Care Administration and Control Authority (FMHACA) is preparing a new directive that compels food processing companies to secure competency certification from the authority before they release their products to the market.

Ethiopia: FMHACA to Adopt New Food Compliance ...
FMHACA, 2012. Iodized Salt Control Directive No. 5/2012.Addis Ababa, Ethiopia. FMHACA, 2014. Food Exporters, Importers and Wholesalers Control Directive No. 22/2014 ...

Food Safety Regulations and Enforcement in Ethiopia ...
• Technical support Private, Governmental and Non Governmental Health Facility, Health and Health related organization and Institutions through Planning, Coordinating, Organizing, preparing...

Shitahun Yenet - • Core ProcessoOwner - • Addis Ababa ...
Practice guideline for the treatment of patients with ... Guideline for Registration of Medicines 0 FOOD, MEDICINE AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA (FMHACA) GUIDELINE FOR GUIDELINE FOR REGISTRATION OF MEDICINES Drafts of this guideline were reviewed in clinical conferences and by distribution for

Standard Treatment Guideline For Ethiopia
Download Guidelines for WHO Pre-qualified Medicines through Collaborative Registration Procedure File size: 159 KB Downloads: 3