NORMATIVE INSTRUCTION NO. 15, DATED NOVEMBER 17, 2009

It provides for the time periods, schedule and priorities for the first implementation stage of the active pharmaceutical ingredients (API) registration, defined in the Board of Directors Resolution - RDC No. 57, dated November 17, 2009, to which the companies established in the country and performing the activities of manufacture or import of active pharmaceutical ingredients have to adjust themselves.

The Board of Directors of the Brazilian Health Regulatory Agency, pursuant to the powers vested in it under art. 11, item IV, of ANVISA’s Regulation approved by Decree no. 3029, dated April 16, 1999, and pursuant to provisions in item II and in §§ 1 and 3 of article 54, and in item II of article 55 of the Internal Regulation approved under the terms of Attachment I to ANVISA’s Regulation no. 354, dated August 11, 2006, published again in the Federal Official Gazette dated August 21, 2006, during the meeting held on April 14, 2009,

whereas health is a right of every person and the duty of the State, guaranteeing political, social and economic measures aimed at reducing the risk of disease and of other worsening to the universal and equal access to the actions and services for its promotion, protection and recovery, under the terms of article 196 of the Constitution of the Brazilian Federative Republic, dated October 5, 1988;

whereas the healthcare actions and services have public relevance, under the terms of article 197 of the Constitution and that the Government is responsible for defining, under the terms of the law, its regulation, inspection and control;

whereas the provisions set forth in Law no. 6360, dated September 23, 1976, and in Decree no. 79094, dated January 5, 1977, regarding the health regulatory system to which the medications, active ingredients, pharmaceutical ingredients, similar products and other products are subject;

whereas Law no. 6437, dated August 20, 1977, which provides for the infringements of the federal health laws and sets forth the respective penalties;

whereas Anvisa's institutional purpose of promoting health protection of the population and its duty of coordinating the Brazilian Health Regulatory System, as set forth in art. 6 and in items I, III and XXII of article 7 of Law No. 9782, dated January 26, 1999;

whereas the guidelines, the priorities and the responsibilities set forth in the Brazilian Medications Policy, enacted by Regulation no. 3916/MS/GM, dated October 30, 1998, aimed at guaranteeing conditions for safety and quality of the medications consumed in the country, promote the reasonable use and the population's access to the ones deemed to be essential;

whereas the provisions set forth in Resolution no. 338, dated May 6, 2004, of the Brazilian Health Board, which approves the Brazilian Pharmaceutical Assistance Policy, defining its
principles and strategic axes, including qualification of the existing pharmaceutical assistance services and construction of the Health Regulatory Policy that guarantees the population’s access to safe, efficient and qualified services and products;

whereas the Active Pharmaceutical Ingredients Program created through Resolution RDC no. 250, dated September 13, 2005;

whereas RDC Resolution no. 30, dated May 15, 2008, which provides for the compulsory registration of active pharmaceutical ingredients with Anvisa;

whereas Regulation no. 978 dated May 16, 2008, which provides for the list of strategic products, with the Brazilian Unified Health System, with the purpose of cooperating with the development of the Health Industrial Hub and creates the Commission for Review and Update of the referred list;

whereas the need to regulate the active pharmaceutical ingredients registration in Brazil, in order to improve quality control of those products in the country and the health requisites to guarantee efficacy and safety of the medications;

whereas the existence of specific standard, Resolution RDC No. 57, dated November 17, 2009, which provides for the registration of active pharmaceutical ingredients among other provisions, RESOLVES:

Art. 1 The schedule and the priorities for the first implementation stage of the active pharmaceutical ingredients registration is hereby approved, under the terms of Anvisa's Board of Directors Resolution no. 57, dated November 17, 2009.

CHAPTER I
THE DEFINITION OF THE ACTIVE PHARMACEUTICAL INGREDIENTS TO BE SUBMITTED IN THE FIRST IMPLEMENTATION STAGE OF THE RESPECTIVE HEALTH REGISTRATION

Art. 2 The following active pharmaceutical ingredients will be subject to the first implementation stage of the health registration with Anvisa, according to the priority criteria and other provisions defined in the Board of Directors Resolution no. 57, dated November 17, 2009:

I. Cyclosporine
II. Clozapine
III. Clindamycin hydrochloride
IV. Cyclophosphamide
V. Ciprofloxacin
VI. Methotrexate
VII. Carbamazepine
VIII. Lithium carbonate
IX. Phenytoin
X. Phenytoin sodium
XI. Lamivudine
XII. Penicillamine
XIII. Thiabendazole
XIV. Efavirenz
XV. Nevirapine
XVI. Rifampicin
XVII. Ritonavir
XVIII. Zidovudin
XIX. Aciclovir
XX. Ampicillin
CHAPTER II
THE TIME PERIODS FOR THE ADEQUACIES RELATED TO THE FIRST IMPLEMENTATION STAGE OF THE ACTIVE PHARMACEUTICAL INGREDIENTS REGISTRATION

Art. 3 For the active pharmaceutical ingredients defined in Art. 2 of the Normative Instruction herein, the following deadlines are established for the respective adequacies related to provisions set forth by RDC No. 57, dated November 17, 2009:

§ 1. As of February 01, 2010 the companies established in the country that perform activities of manufacturing or import of active pharmaceutical ingredients should petition the request for health inspection by Anvisa in order to issue the respective Certificate of Good Manufacturing Practices of Intermediary Products and Active Pharmaceutical Ingredients.

§ 2. As of July 01, 2010 the companies established in the country performing the activities of manufacture or import of the active pharmaceutical ingredients defined in the heading of this Article should petition the respective request for registration with Anvisa.

§ 3. The date of December 30, 2010 is hereby defined as the limit date to petition for the health registration of the active pharmaceutical ingredients referred in the Normative Instruction herein.

Art. 4. This Normative Instruction shall be in full force and effect as of its publication date.

DIRCEU RAPOSO DE MELLO