NORMATIVE INSTRUCTION NO. 3, DATED JUNE 28, 2013

It provides for the time periods and the schedule for the second implementation stage of the active pharmaceutical ingredients 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 and the medications and intermediary products containing them 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 June 20, 2013, resolves:

Art. 1 The schedule for the second 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.

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

I - The APIs Azithromycin, Benzyl penicillin, Cabergoline, Carboplatin, Cephalexin, Cephalothin, Ceftazidime, Cisplatin, Clarithromycin, Ceftriaxone as well as their respective salts, esters, ethers and hydrates;

II - The salts, esters, ethers and hydrates of the active pharmaceutical ingredients listed in the Normative Instruction no. 15/09.

Art. 3 For purposes of trade and use of the APIs referred to in this Normative Instruction, the following time periods are defined for adequacy:

I – As of January 1st, 2014 the companies established in the country performing the activities of manufacture or import of active pharmaceutical ingredients, medications and intermediary products containing the active pharmaceutical ingredients defined in Items I and II of article 2 should petition the respective registration with ANVISA.

II - As of January 1st, 2015 the companies established in the country performing the activities of manufacture or import of active pharmaceutical ingredients, medications and intermediary products containing the active pharmaceutical ingredients defined in Items I and II of article 2
that have not petitioned or for which the petition for registration has been denied by Anvisa will
not be allowed to import and/or trade the API in question.

III - As of January 1st, 2016 the companies established in the country performing the activities
of manufacture or import of active pharmaceutical ingredients, medications and intermediary
products containing the active pharmaceutical ingredients defined in Items I and II of article 2
that do not have the respective registrations granted by Anvisa will not be allowed to import
and/or trade the API in question.

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

DIRCEU BRÁS APARECIDO BARBANO