

7th PART

*Cadastral of
Active Pharmaceutical Ingredients*

**ANVISA Resolution – RDC n. 30,
of May 15th, 2008**

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The Collegiate Board of Directors of the Brazilian Sanitary Surveillance Agency, in the use of the attribution vested in it by article 11, clause IV, of the Regulation of ANVISA approved by Decree n. 3.029, of April 16, 1999, and in view of what is determined by the proposition II and paragraphs 1st and 3rd of the article 54, of the Internal Regulation approved by the terms of the Annex I of the ANVISA's Bylaw n. 354, of August 11th, 2006, republished in the Federal Official Journal of August 21, 2006, in meeting held on April 15th, 2008, and

- whereas the Resolution – RDC 250, of September 13th, 2005, that creates the Pharmaceutical Active Ingredients Program and its article 6th that establishes the registry for the active pharmaceutical ingredients used in the country as one of its technical-administrative activities;
- whereas the need of a sanitary control of the production, import, export, fractionate, store, transport and distribute pharmaceutical ingredients;
- whereas the need to standardize the referring sanitary actions of monitoring pharmaceutical ingredients;
- whereas the need to ensure rastreability and to support inspection actions for pharmaceutical ingredients, adopts the following Resolution of the Collegiate Board of Directors and I, the Chairman, determine its publication:

Article 1 – To determine, by means of this resolution, the obligation of all established companies in this country that exercise the activities of manufacturing, import, export, fractionate, store, transport and distribute active pharmaceutical ingredients, to register in the ANVISA'S cadastre all active pharmaceutical ingredients with which they work.

Paragraph 1 – Compounding pharmacies and companies which the activity is only to transport are excluded of this obligation.

Paragraph 2 – Manufacturers of pharmaceutical products that use active pharmaceutical ingredients for their own production, will have to register only the ingredients which are imported.

Article 2 – The ingredients must be registered using the electronic petition system available on www.anvisa.gov.br, in which additional instructions and definitions can be found for the correct fulfilling of the forms.

Article 3 – In the case of active pharmaceutical ingredient not purchased directly from the manufacturer, the data supplied must contain all information about manufacturers, retailers and distributors of any kind.

Paragraph 1 – The supplied information must be sufficient for the correct identification of the manufacturer and retailers. Abbreviations are not allowed.

Article 4 – The information supplied to the ANVISA'S cadastre in the occasion of the pharmaceutical active ingredient registration is of entire responsibility of the involved companies.

Article 5 – At any time, the company will have the option to cancel any of its registered pharmaceutical active ingredients, to change the information already provided or to register new ingredients in its cadastre, in a way that its information in the ANVISA'S cadastre is always up to date, and it contains only the ingredients with which the company effectively works.

Article 6 – At the end of 180 (one hundred and eighty days) period, starting at the date of the publication of this resolution, the companies will only be able to commercialize active pharmaceutical ingredients registered in its ANVISA'S cadastre.

Article 7 – The non-observance or disobedience to what is described in the present Resolution configures a sanitary nature infraction, and the infractors are subject to the penalties foreseen in law.

Article 8 – This Resolution enters into force on the date of its publication.

DIRCEU RAPOSO DE MELLO