The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency, in the exercise of the powers vested by Article 11, Subsection IV, from the Regulation approved by Decree no. 3,029, dated from April 16th, 1999, and in view of the provisions of Subsection II and Paragraphs 1 and 3 of Article 54 of the Internal Regulations approved in accordance with Annex I of ANVISA Ordinance no. 354, of August 11th, 2006, republished on the Official Gazette on August 21st, 2006, in meeting held on September 26th, 2006, and considering the provisions of Article 196 of the Brazilian Federal Constitution of 1988, which establishes that health is a right to all and a duty of the State, guaranteed by social and economic policies aimed at universal and equal access to healthcare actions and services;

considering the institutional mission of Anvisa, which seeks to protect and promote the population’s health by ensuring the sanitary safety of products and services and by participating in the provision of access;

considering the need to regulate Subsection VII and Paragraph 2 of Article 16 of Law no. 6,360, of September 23rd, 1976, amended by Law no. 10,742, of October 6th, 2003, which sets forth that the registration of health products is subject, among other requirements, to the submission of economic information;

considering Public Consultation no. 92, of December 21st, 2005 (Official Gazette of December 23rd, 2005), in which civil society had the opportunity to provide feedback regarding the submission of economic information on health products;

considering the need to reduce the asymmetry of information regarding health products, which constitutes a fundamental instrument for the work of those involved in health management activities and for greater clarification for users of these products;

hereby adopts the following Resolution and I, Director-President, determine its publication:

Article 1. Upon submission of registration or revalidation applications regarding health products, companies shall submit an ECONOMIC INFORMATION REPORT to the Center of Economic Assistance in Regulation - NUREM, containing the following information:
a) product price quoted in other countries;

b) the potential number of patients for which the product is intended;

c) the intended price in the domestic market, with a breakdown of its tax burden;

d) the discrimination of the product commercialization proposal, including costs planned for sales effort and for advertising and publicity;

e) a list of substitute products in the market, along with their respective prices.

Paragraph 1. The list of health products whose economic information shall be submitted shall be published in Specific Resolution RE/ANVISA.

Paragraph 2. The information shall be provided in hard copies and electronic versions, as recommended in the GUIDANCE TO PREPARE THE ECONOMIC INFORMATION REPORT herein attached and enclosed to a worksheet to be made available on website http://www.anvisa.gov.br/monitora/index.htm.

Article 2. In the impossibility of submitting the ECONOMIC INFORMATION REPORT before the granting of the Health Product Registration or the renewal thereof, the company shall submit this report within 30 (thirty) days after the date of publication of the registration or registration renewal.

Paragraph 1. If the submitted information is inconsistent or incomplete, the Center of Economic Assistance in Regulation - NUREM shall send a requirement to the company, which shall be fulfilled within 15 (fifteen) days, counted from its receipt.

Paragraph 2. Failure to meet the requirement, provision of false information or failure to meet the deadlines addressed in Article 2 and Paragraph 1 hereof shall result in the suspension of product sales, pursuant to Article 10, Subsection XXXI, of Law no. 6,437, dated from August 20th, 1977.

Article 3. As to registration revalidations, the provisions hereof shall solely apply to applications submitted after 60 days this Resolution has come into force.

Article 4. This Resolution shall come into force on the date of its publication.

DIRCEU RAPOSO DE MELLO
ANNEX

GUIDANCE TO PREPARE THE ECONOMIC INFORMATION REPORT

1. Cover sheet with the following information

1.1. Title with the words "Economic Information Report", highlighted, in bold and capital letters.

1.2. Company Name.

1.3. Product Information:

1.3.1. Risk classification;

1.3.2. Product technical name;

1.3.3. Product commercial name and/or model;

1.3.4. Detailed product description.

1.4. Subject of Application - Registration or Registration Revalidation

2. Economic Information

2.1. Product price quoted in other countries

2.1.1. Inform the ex-factory price, along with the discrimination of taxes and distribution margin, with due evidence of its source in the country of origin and, if applicable, in the following countries:

2.1.1.1. Germany;

2.1.1.2. Australia;

2.1.1.3. Canada;

2.1.1.4. Spain;

2.1.1.5. United States of America;

2.1.1.6. France;

2.1.1.7. Italy;

2.1.1.8. Japan;
2.1.1.9. Portugal;

2.1.1.10. United Kingdom.

2.2. Number of yearly potential patients to whom the product is intended

2.2.1. Inform the potential number of patients to use the product or that will be subject to exams, indicating on which sources this estimation was based, along with the calculation methodology.

2.2.1.1. In the case of equipment, inform its lifetime and the number of times it can be used.

2.2.1.2. In the case of in-vitro diagnostic products, inform the number of tests to be performed per kit.

2.3. The ex-factory price intended to be quoted in the domestic market, along with the breakdown of its tax burden.

2.3.1. Inform the ex-factory price specifying the applicable taxes and distribution margins.

2.4. Discrimination of the product commercialization proposal

2.4.1. Inform planned costs with sales effort aimed at healthcare professionals, including support to travels and events, research funding, propagandists, etc.

2.4.2. Discriminate expenses for publicity and advertising.

2.5. List of substitute products in the market.

2.5.1. Inform the list of substitute or similar products in the market, along with their corresponding prices.

2.5.2. If there is no substitute product, the company must submit a justification, identifying the product’s technological innovations, advantages and efficacy studies, if applicable, in comparison with the products used for the same purpose.