

COMPLEMENTARY AGREEMENT TO THE AGREEMENT OF SCIENTIFIC AND
TECHNOLOGICAL COOPERATION BETWEEN THE GOVERNMENT OF THE
FEDERATIVE REPUBLIC OF BRAZIL AND THE GOVERNMENT OF THE
PEOPLE'S REPUBLIC OF CHINA ON SURVEILLANCE OF DRUGS
AND HEALTH RELATED PRODUCTS

The Government of the Federative Republic of Brazil

and

The Government of the People's Republic of China
(hereinafter referred to as the "Parties"),

Within the framework of the Agreement for Scientific and Technological Cooperation signed in Beijing on the 25th of March, 1982 between the Government of the Federative Republic of Brazil and the Government of the People's Republic of China and with a view to enhancing friendly relationship between the Governments and the peoples of the two countries and to strengthening cooperation between them.

Realizing the importance of working together to address common concerns to insure safety and efficacy of therapeutic products including traditional drugs and medical devices in their respective countries.

Have agreed as follows:

ARTICLE I
Objectives

The Objectives of this Complementary Agreement are:

- I. to develop understanding of regulatory requirements and procedures for drug regulation compliance;

- II. to assist officials and technical specialists in each country to develop their professional competencies through the knowledge of regulatory demands and procedures of the other country; and
- III. to establish a framework for cooperative relationship between both Parties.

ARTICLE II

Areas of Cooperation

I. Exchange of Information

Both Parties agree to establish avenues of communication to facilitate the exchange of information about the policies, management, standards, testing technology, quality control, market compliance, regulatory compliance requirements, import and export regulations for therapeutic products.

II. Personnel Exchange

Both sides agree to provide such assistance as is possible in the visits, exchanges, and cooperation between the management and technical personnel from each other.

ARTICLE III

Executing Agencies

The present Complementary Agreement will be executed by the Brazilian Health Surveillance Agency and the State Food and Drug Administration of the People's Republic of China, hereinafter referred to as Executing Agencies.

ARTICLE IV

Work Plan

Both Executing Agencies agree to develop a relevant work plan each two years from the entry in to force of this Complementary Agreement. It is recognized that the implementation of the work plan needs the efforts by both and will be subject to the availability of staff and funding.

ARTICLE V
Conditions of Exchange of Information

Information exchanged or produced under this Complementary Agreement shall be treated as confidential and for the use of the Parties only, unless otherwise mutually decided.

ARTICLE VI
Financial Arrangements

Each Party will bear its own costs in relation to initiatives undertaken under this Complementary Agreement, unless other specific arrangements are agreed upon by both Executing Agencies in the Work Plan.

ARTICLE VII
Entry in to Force and Termination

This Complementary Agreement shall come into force on the date of its signature and remain in force for a period of 5(five) years. If either Party does not give to the other a written notice, 6 (six) months in advance, of its intention to terminate it, this Complementary Agreement will be automatically extended for another 5 (five) years and will be further extended in like manner.

Done in Beijing on the 24th of May, 2004, in two originals each in the Portuguese, Chinese and English languages, all texts being equally authentic. In case there is any divergence of interpretation, the English version shall prevail.



FOR THE GOVERNMENT OF THE
FEDERATIVE REPUBLIC OF BRAZIL



FOR THE GOVERNMENT OF THE
PEOPLE'S REPUBLIC OF CHINA