



# Life Sciences in Brazil

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Food, Drug, Agriculture, Health Care, Biotechnology and Biodiversity

June 2006

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### News

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- Pharmaceutical Substances
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This is the sixty edition of **Life Sciences in Brazil**, an electronic newsletter with information on the regulations issues and/or proposed, in the past month, and relevant matters of Food, Drug, Agriculture, Health Care, Biotechnology, Biodiversity, which was prepared in English only, by the members of our Life Sciences Group.

We hope this publication is informative. If you believe this publication will also be useful to others, we will be glad to include their contact information in our mailing. Please send their names and e-mail address to [pna@pinheironeto.com.br](mailto:pna@pinheironeto.com.br).

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### **MEDICINES**

Decree No. 5775 enacted on May 10, 2006 authorized pharmacies and drugstores to shatter medicines. ANVISA also issued Resolution RDC No. 80 of May 12, 2006 establishing technical requirements for the shattering.

Only medicines not subject to special control can be shattered in Brazil and shattering can only be performed by the pharmacist upon presentation of the medical recipe, except for Over-the-Counter medicines.

### **PHARMACEUTICAL SUBSTANCES**

ANVISA adopts the Common Brazilian Denominations (“DCB”) to indicate the chemical substance used as a medicine or the active ingredient of the product approved by the federal authority responsible for the Sanitation Surveillance (Ordinance No. 971, from August, 10, 1993).

ANVISA has recently updated the DCB including, changing, excluding and correcting the number approved by the Chemical Abstracts Service (CAS) and including the CAS number or bibliographic reference, respectively on the Brazilian Common Denominations (DCB) of 2004 (ANVISA Resolution - RDC No. 83 of May 16, 2006).

Companies have 360 days for to apply to the provisions of this resolution.

### **FOOD LABELING**

**REMINDER:** The deadline for the companies engaging in the manufacture, importation or distribution of food products to conform to the new food labeling rules, as per Resolutions RCD 359/03 and 360/03, is drawing near (July 30, 2006).

### **PEPPER**

MAPA approved the new Technical Regulations on the Identity and Quality of Black Pepper for internal sale, importation and exportation, as well as the related sampling, supplementary procedures and classification schedule. (Normative Ruling No. 10, of May 15, 2006).

### **PUBLIC CONSULTATIONS - MAY / 2006**

Before a regulation enters into force, ANVISA or MAPA publishes the proposed regulation for “Public Consultation”. Comments and suggestions can be submitted by any interested party within a certain period of time counting from the publication date of the Public Consultation at the Official Gazette of the Federal Executive. During such period, the Public Consultations are available at ANVISA website [www.anvisa.gov.br](http://www.anvisa.gov.br) or at MAPA website [www.agricultura.gov.br](http://www.agricultura.gov.br).



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as the case may be. The regulation will only come into force after the publication as a “Resolution”, “Normative Ruling”, “Ordinance” or the like.

| No.                                   | Subject Matter   | Publication Date |
|---------------------------------------|--|------------------|
| <b>Food</b>                           |  |                  |
| 24                                    | Technical Rules on Food Additives, in order to establish their use and maximum limits for the Food, Fruit and Vegetable Category –Fruit Marmalade Subcategory.   | May 12, 2006     |
| 27                                    | Mercosul Technical Rules on Food Additives, to establish their use and maximum limits for the Cereal and Cereal Based Products                                   | May 25, 2006     |
| <b>Pesticides and Wood Preservers</b> |  |                  |
| 25                                    | Proposal of Technical Regulation for the C32 – CLETODIM, an active ingredient contained in the Report on Pesticide Active Ingredients and Wood Preservers.       | May 15, 2006     |
| 26                                    | Proposal of Technical Regulation for the D36 - DIPHENOCONAZOL, an active ingredient contained in the Report on Pesticide Active Ingredients and Wood Preservers. | May 25, 2006     |
| 28                                    | Proposal of Technical Regulation for the B27 – BROMADIOLONE, an active ingredient contained in the Report on Pesticide Active Ingredients and Wood Preservers.   | May 15, 2006,    |
| <b>Animals</b>                        |  |                  |
| Ord. 112                              | Normative Ruling related to the procedures for the importation of feed products (Ordinance of the Agribusiness Protection Office of MAPA)                        | May 10, 2006     |

### GLOSSARY

ANVISA – National Supplementary Health Agency

MAPA – Ministry of Agriculture, Cattle Breeding and Supply

This is a periodic publication prepared in English language only by the Life Sciences practice group of Pinheiro Neto Advogados. This issue was compiled by Camila Martino Parise, Laura de Barros Mello, Patricia Helena B. de Souza, Julia Augusto Pereira Lima and Mariana Alonso Tomazelli. Any request related to this publication, please address to Ms. Camila Martino Parise ([camila@pinheironeto.com.br](mailto:camila@pinheironeto.com.br)).