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ABOUT THIS NEWSLETTER

Life Sciences in Brazil is a newsletter with information on recent legislation in the areas of Agriculture, Health Care, Innovation, Biotechnology and Biodiversity. The publication is prepared monthly, in Portuguese and in English, by the **Life Sciences** group of **Pinheiro Neto Advogados**, under coordination of **Angela Fan Chi Kung** (akung@pn.com.br) e **Camila Martino Parise** (cparise@pn.com.br).

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PHARMACEUTICALS AND PHARMACEUTICAL INPUTS

Amendment to RDC No. 26/14

RESOLUTION RDC ANVISA No. 93 OF JULY 12, 2016

Amends RDC No. 26 of May 13, 2014, which provides for registration of medicinal herbs as well as registration and notification of traditional medicinal herb preparations ('traditional phytotherapeutic products').

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MEDICAL DEVICES

Minimum identity and quality requirements for surgical gloves and gloves for non-surgical procedures

RESOLUTION RDC ANVISA No. 94 OF JULY 27, 2016

Updates the normative technical reference of RDC No. 55 of November 4, 2011, which establishes the minimum identity and quality requirements for surgical gloves and gloves for non-surgical procedures made of natural rubber, synthetic rubber, mix of natural rubber with synthetic rubber, and polyvinyl chloride, under the public health control regime.

Extends the period for adjustment of the technical reports of registers and records

RESOLUTION RDC ANVISA No. 95 OF JULY 17, 2016

Extends the period for adjustment of the technical reports of registers and records in effect of RDC No. 36 of August 26, 2015, which provides for classification of risk, regimes for controlling record and registration, as well as requirements on labeling and instructions to use in vitro diagnostic devices, including their instruments, and makes other provisions; and extends the period for adjustment of the technical reports of registers and records in effect of RDC No. 40 of August 26, 2015, which deals with requirements for registration of medical devices.

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AGROCHEMICALS

Maintenance of the active ingredient Lactofen in agrochemical products

RESOLUTION RDC ANVISA No. 92 OF JULY 7, 2016

Provides for the maintenance of the active ingredient Lactofen in agrochemical products due to its toxicological reevaluation.

Amendment to Normative Ruling 36/09

NORMATIVE RULING SDA No. 15 OF JULY 7, 2016

Amends article 29 of Normative Ruling No. 36 of November 24, 2009 (Establishes guidelines and requirements for researches and experiments on agrochemicals and related products, and for accreditation of research, teaching and technical assistance public and private entities, with a view to issuing reports on agronomic efficacy and feasibility, on phytotoxicity and on wastes for registration of agrochemicals and related products).

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COSMETICS, HYGIENIC PRODUCTS AND PERFUMES

Amendment to Law 4,946/06

RIO DE JANEIRO STATE LAW No. 7,328 OF JULY 7, 2016

Amends Law 4,946 of December 20, 2006, which provides for the compulsory use of security seals on packaging of products manufactured by the cosmetics industry that are marketed in the State of Rio de Janeiro.

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ANIMAL, PLANT, AGRICULTURAL AND CATTLE BREEDING PRODUCTS

Technical Regulation on Wheat

NORMATIVE RULING MAPA No. 23 OF JULY 1, 2016

Amends article 2 of Normative Ruling No. 38 of November 30, 2010 (Establishes the Technical Regulation on Wheat, defining its official classification standards, quality and identity requirements, sampling, form of presentation, marking or labeling).

Labeling of foods that contain lactose	FEDERAL LAW No. 13,305 OF JULY 4, 2016 Adds article 19-A to Decree-Law No. 986 of October 21, 1969, which "institutes basic rules on foods", to provide for labeling of foods that contain lactose.
Technical Regulation on hygienic and health conditions as well as good manufacturing practices for manufacturers of products intended for animal feed	NORMATIVE RULING SDA No. 14 OF JULY 6, 2016 Amends the provision set out in item 8.3 of Normative Ruling No. 4 of February 23, 2007 (Approves the Technical Regulation on hygienic and health conditions as well as good manufacturing practices for manufacturers of products intended for animal feed and the inspection procedures).
Amendment of Resolution CFMV No. 844/06	RESOLUTION CFMV No. 1,115 OF JULY 17, 2016 (published on July 11, 2016) Amends Resolution CFMV No. 844 of September 20, 2006 (Defines that it is exclusively incumbent upon veterinarians to attest the health and the death of animals, and to certify that products of animal origin are healthy).
Cotton in Plume	NORMATIVE RULING MAPA No. 24 OF JULY 14, 2016 Establishes the Technical Regulation on Cotton in Plume, defining its official classification standard, including its identity and quality standards, sampling, presentation form, marking or labeling.
Analysis of the application for the registration of cultivar exclusively intended for production of seeds for exportation	ORDINANCE SDA No. 67 OF JULY 15, 2016 Determines that priority shall be given to the analysis of the application for registration of cultivar exclusively intended for production of seeds for exportation, with a view to obtaining enrollment with the Register of Cultivars (RNC).

Reconstitution of Powder Milk by dairy industries under Federal Control

NORMATIVE RULING SDA No. 26 OF JULY 21, 2016

Authorizes, for a one-year period, the reconstitution of powder milk by dairy industries under Federal Control, previously certified to produce UHT milk and pasteurized milk, which are located in the area of operation of Northeastern Brazil Development Authority (SUDENE), which was hit by the draught, with a view to producing reconstituted UHT/pasteurized milk for direct sale to the public, with due regard for the rules set out in Normative Ruling No. 14 of April 22, 2013.

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SUS

Inclusion of the Rapid Diagnostic Test for the Detection of Hepatitis Virus (HBV) in SUS

ORDINANCE SAS No. 828 OF JULY 5, 2016

Includes the Procedure relating to the Rapid Diagnostic Test for the Detection of Hepatitis Virus (HBV) in the List of Procedures, Pharmaceuticals, Ortheses, Prostheses and Special Materials of SUS.

Restriction on the use of beta interferon 1A 6,000,000 UI (30 mcg) for treating multiple sclerosis

ORDINANCE SAS No. 27 OF JULY 6, 2016

Makes public the decision to restrict the use of beta interferon 1A 6,000,000 UI (30 mcg) for treating relapsing-remitting multiple sclerosis in SUS, as per an update of the Ministry of Health Protocol, in the ambit of SUS.

Non-inclusion of omalizumab for the treatment of severe allergic asthma

ORDINANCE SAS No. 28 OF JULY 6, 2016

Makes public the decision of not including in SUS the drug omalizumabe for treatment of severe allergic asthma not controlled with medium or high-dose inhaled corticosteroids associated with long-acting beta 2-agonist.

Inclusion of procedures in the List of SUS

ORDINANCE SAS No. 933 OF JULY 26, 2016

Includes procedures in the List of Procedures, Pharmaceuticals, Ortheses, Prostheses and Special Materials of SUS (Detection of RNA of HTLV-1 virus and research on Anti-HTLV-1 antibodies (Western Blot)).

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CLINICAL PROTOCOL AND THERAPEUTIC GUIDELINES

Endometriosis	ORDINANCE SAS No. 879 OF JULY 12, 2016 Approves the Clinical Protocol and Therapeutic Guidelines on Endometriosis.
Angioedema due to acquired C1-esterase inhibitor (C1-INH) deficiency	ORDINANCE SAS No. 880 OF JULY 12, 2016 Approves the Clinical Protocol and Therapeutic Guidelines on Angioedema due to acquired C1-esterase inhibitor deficiency (C1-INH).
Use of Zidovudine for treating Adults with Leukemia/Lymphoma	ORDINANCE SVS No. 54 OF JULY 18, 2016 Approves the Protocol on the use of Zidovudine for treating Adults with Leukemia/Lymphoma Associated with HTLV-1 Virus.

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ANVISA

Good Practices on Water Supply System or Collective Alternative Solution of Water Supply	RESOLUTION RDC No. 91 ANVISA OF JUNE 30, 2016 Deals with Good Practices on Water Supply System or Collective Alternative Solution of Water Supply in Ports, Airports and Borders.
Delegation of powers to evaluate pre-shipment authorization requests of biological products	ORDINANCE ANVISA No. 1,521 OF JULY 26, 2016 Delegates to civil servants of the Health Control Coordination in Ports, Airports, Borders and Bonded Warehouses in the State of Goiás powers to evaluate, for two years, extended for the same period, pre-shipment authorization requests of biological products, pursuant Procedure 2C of RDC 81/2008.

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MISCELLANEOUS

Multiple Sclerosis Awareness Week	SÃO PAULO STATE LAW No. 16,277 OF JULY 6, 2016 Institutes the "Multiple Sclerosis Awareness Week".
Surveillance and control measures to be taken whenever there is any situation of imminent danger because of the presence of the mosquito that transmits dengue and chikungunya fever	SÃO PAULO MUNICIPAL LAW No. 16,498 OF JULY 20, 2016 Amends the law that deals with surveillance and control measures to be taken whenever there is any situation of imminent danger to public health because of the presence of the mosquito that transmits dengue and chikungunya fever, and makes other provisions.
Amendment to Ordinance No. 3,388/13	ORDINANCE MS No. 1,325 OF JULY 22, 2016 Amends Ordinance GM/MS No. 3,388 of December 30, 2013, which deals with National Cytopathology Qualification in colorectal cancer prevention (QualiCito).
Oximetry screening for all newborns	SÃO PAULO MUNICIPAL LAW No. 16,527 OF JULY 25, 2016 Deals with pulse oximetry screening for all newborns in the hospital nurseries of the City of São Paulo, and makes other provisions.

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PUBLIC CONSULTATIONS (CP)

Before a regulation comes into force, MS, 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 as from the publication date of the Public Consultation in the Official Gazette of the Federal Executive. During such period, the Public Consultations are available at www.anvisa.gov.br or www.agricultura.gov.br, the ANVISA and MAPA websites, respectively. A regulation only comes into force after it is published as a "Resolution", "Normative Ruling", "Ordinance" or the like.

Rule / Public Consultation (CP)	Subject	Publication Date	Term
SCTIE – CP No. 15 of July 4, 2016	Makes public an invitation to the civil society to submit comments and suggestions on the preliminary recommendation made by the Brazilian Committee on Technology Incorporation regarding the proposal for including in SUS rivastigmine transdermal patch for the treatment of dementia and Alzheimer's disease, as presented by Novartis Biociências S.A.	July 6, 2016	--
ANVISA – CP No. 226 of July 7, 2016	Establishes a period for submission of comments and suggestions to the text of the proposal dealing with procedures for inclusion of regional botanical species classified as N3 in the base list of flavoring components, pursuant to RDC No. 2 of January 15, 2007, which approves the technical regulation on flavoring additives.	July 12, 2016	60 days
ANVISA – CP No. 227 of July 7, 2016	Establishes a period for submission of comments and suggestions to the text of the proposal establishing criteria for provisional authorization to market foods and beverages containing flavoring components from regional botanical species classified as N3 by RDC No. 2 of January 15, 2007, which approves the Technical Regulation on Flavoring Additives.	July 12, 2016	60 days
SCTIE – CP No. 16 of July 11, 2016	Makes public an invitation to the civil society to submit comments and suggestions on the preliminary recommendation made by the Brazilian Committee on Technology Incorporation regarding the proposal for inclusion in SUS of intraoperative radiotherapy for treating early stages of breast cancer in addition to partial mastectomy, as presented by CARL ZEISS MEDITEC AG.	July 13, 2016	--
ANVISA – CP No. 228 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that changes the Maximum Residue Level (MLR) from 0.02 to 0.05 mg/kg and the Safety Period from 269 to 180 days for the culture of sugar cane, under the pre/post foliar application mode, in the compendium of the active ingredient A41 - AMICARBAZONE.	July 28, 2016	30 days

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Rule / Public Consultation (CP)	Subject	Publication Date	Term
ANVISA – CP No. 229 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution for adding the culture of millet and sorghum, under the foliar application mode, with Maximum Residue Level (MLR) of 0.07 mg/kg and Safety Period of 14 days, to the compendium of the active ingredient C70 –CHLORANTRANILIPROLE.	July 28, 2016	30 days
ANVISA – CP No. 230 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution for changing the Maximum Residue Level (MLR) from 0.1 to 0.5 mg/kg, in the culture of rice, under the foliar application mode, in the compendium of the active ingredient M02 - MANCOZEB.	July 28, 2016	30 days
ANVISA – CP No. 231 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that includes the culture of watermelon, under the foliar application mode, with Maximum Residue Level (MLR) of 01 mg/kg and Safety Period of 07 days; strawberry, raspberry, and blueberry, under the foliar application mode, with Maximum Residue Level (MLR) of 02 mg/kg and Safety Period of 03 days; guava, persimmon, fig, cucumber, pumpkin, zucchini, chayote and bur gherkin, under the foliar application mode, with Maximum Residue Level (MLR) of 0.7 mg/kg and Safety Period of 01 day; peach, plum, quince and pear, under the foliar application mode, with Maximum Residue Level (MLR) of 03 mg/kg and Safety Period of 01 day; pepper, eggplant, scarlet eggplant, and chili pepper, under the foliar application mode, with Maximum Residue Level (MLR) of 01 mg/kg and Safety Period of 01 day, in the compendium of the active ingredient P43 - PYRIMETHANIL.	July 28, 2016	30 days
ANVISA – CP No. 232 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that increases the Maximum Residue Level (MLR) from 0.1 to 0.3 mg/kg for the culture of soybean, in the compendium of the active ingredient I15 - IMAZAMOXI.	July 28, 2016	30 days
ANVISA – CP No. 233 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that includes the culture of tomato, under the foliar application mode, with Maximum Residue Level (MLR) of 0.3 mg/kg and Safety Period of 01 day, in the compendium of the active ingredient E26 - ESPIROMESIFEN.	July 28, 2016	30 days
ANVISA – CP No. 234 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that includes the culture of corn, under the foliar application mode, with the Maximum Residue Level (MLR) of 0.01 mg/kg and Safety Period of 42 days, in the compendium of the active ingredient C18 - CHLOROTHALONIL.	July 28, 2016	30 days

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Rule / Public Consultation (CP)	Subject	Publication Date	Term
ANVISA – CP No. 235 of July 27, 2016	Establishes a period for submission of comments and suggestions relating to the proposed Resolution that includes the culture of beans, under the foliar application mode, with Maximum Residue Level (MLR) of 0.01 mg/kg and Safety Period of 14 days and the culture of soybean, under the foliar application mode, with Maximum Residue Level (MLR) of 0.01 mg/kg and Safety Period of 14 days, in the compendium of the active ingredient B39 - BENZYLADENINE.	July 28, 2016	30 days
SCTIE – CP No. 17 of July 28, 2016	Makes public an invitation to the civil society to submit comments and suggestions on the preliminary recommendation made by the Brazilian Committee on Technology Incorporation regarding the proposal for updating the Clinical Protocol and Therapeutic Guidelines on Hepatitis B and Coinfections, with the expansion of use of peginterferon alfa-2a for patients with hepatitis B without delta-agent, of entecavir and tenofovir for patients with hepatitis B with delta-agent and exclusion of interferon alfa-2b (3,000,000 UI, 5,000,000 UI and 10,000,000 UI) – injection, of adefovir (10 mg) tablets and of lamivudine (150 mg and 10 mg) in the oral solution for the treatment of Hepatitis B and Coinfections, as presented by SVS/MS.	July 29, 2016	--

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GLOSSARY

ANVISA – Brazilian Public Health Agency

CFMV – Veterinary Medicine Federal Council

MAPA – Ministry of Agriculture, Cattle Breeding and Supply

MS – Ministry of Health

SAS – Health Support Office

SCTIE - Office of Science, Technology and Strategic Inputs

SDA – Agricultural and Stockbreeding Defense Office

SUS – Integrated Health System

SVS – Health Surveillance Office

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