

RESOLUTION - RDC No. 102, OF AUGUST 24th, 2016

Regulates the procedures for product registration transfer of ownership subject to sanitary surveillance, global transfer of responsibility for clinical testing and updating of data on the operation and certification of companies as a result of corporate transactions or business operations.

The Collegial Board of Directors of the Brazilian National Health Surveillance Agency, in exercise of the powers conferred upon it by art. 15, III and IV together with the art. 7th, III, and IV of Law No. 9,782, of January 26th, 1999, art. 53, V, §§ 1st and 3rd of Internal Regulation approved under Annex I of the Collegial Board of Directors Resolution - RDC No. 61 of February 3rd, 2016, resolved to adopt the following Resolution of the Collegial Board of Directors, as resolved at a meeting held in July 12th, 2016, and I, the Chairman, determine its publication.

CHAPTER I

GENERAL PROVISIONS

Art. 1st This resolution applies to corporate transactions and commercial transactions between companies engaged in activities under the federal health legislation and resulting in the need for updating of registration data for companies' operation and certification, global transfer of responsibility for clinical trial and products registration ownership transfer subject to sanitary surveillance.

Single paragraph. This resolution also covers cases of transactions abroad involving the need to update the scope of ANVISA.

Art. 2nd The procedures established by this resolution applies only to cases in which are kept the conditions and technical and health characteristics of the companies, products and clinical trials.

Art. 3rd The procedures established by this Resolution shall not apply to corporate name changes unrelated to those operations mentioned in art. 1st of this Resolution, which shall be subject to specific regulations.

Article 4th For the purposes of this Resolution, the following definitions shall apply:

I - technical and health characteristics: regular conditions, with ANVISA, of product, company, or clinical trial, at the time immediately prior to the corporate or commercial transaction;

II - scission: corporate transaction in which an entity transfers its equity portions to one or more legal entities, established for this purpose or existing, extinguished the demerged company, if there is any version of all of its assets, or by dividing its capital, if partial to version;

III - succeeded company: legal entity that gives the successor company the rights and obligations on the product object of registration ownership transfer, on the establishment, or the clinical trial liability as a result of corporate or business operations;

IV – successor company: legal entity shall have rights and obligations on the product object of registration ownership transfer, over property, or the clinical trial liability as a result of corporate or business operations;

V - fusion: corporate transaction in which two or more legal entities unite to form a third one, who will succeed them in all rights and obligations;

VI - incorporation: corporate transaction in which one or more legal entities are absorbed by another, which succeeds to all rights and obligations;

VII - commercial operation: operation between companies which result in the sale of assets or a group of assets, without the occurrence of any corporate transaction between them;

VIII - corporate transaction: business act that involves the spin-off, merger or consolidation under Law No. 10,406, of January 10th, 2002 and, on a subsidiary basis of Law No. 6404 of December 15th, 1976;

IX - Mercosur representative: company located in the Receiver Party State (EPR), hired to represent an undertaking company of a product registration in the Producer Party State (EPP), which takes the legal and technical responsibility in the EPR;

X - global transfer of responsibility for clinical trial: change characterized by the change of clinical trial dossiers requesting company, clinical trial notification, drug clinical development dossiers (DDCM), medical devices clinical research dossiers (DICD), programs expanded access, compassionate use programs and providing post-study drug in cases of corporate transactions or business operations, without being given any change of technical and health characteristics contained in the Specific

Special Communication (CEE), Document Import Product under investigation or Special Communication (CE), object of change;

XI -registration ownership transfer: change characterized by the change in the holder of the registration of products subject to sanitary surveillance, in cases of corporate transactions or business operations, without having carried out any change of the technical and health characteristics at the product's registration object of the transfer.

Art. 5th Companies should, as a result of corporate or commercial operations, perform petitioning of registration data update concerning the operation and certification companies, global transfer of responsibility for clinical trial and product registration ownership transfer subject to sanitary surveillance, in accordance to this Resolution.

Single paragraph. In case of successive corporate or commercial operations, it is necessary to perform the petitioning for each transaction.

Art. 6th From the execution of corporate or commercial operation, the company successor subrogated to the rights and obligations of the succeeded company, including with respect to meeting deadlines and suitability rules to health legislation and any restrictive measures on the movement of products.

CHAPTER II

ABOUT THE UPDATE OF REGISTRATION DATA

Art. 7th Companies should docketing with ANVISA, change requests, allocation and or cancellation of Company Operating Permit (AFE) and Special Authorization (AE), update of Good Manufacturing Practices Certificate (CBPF) or Good Distribution and Storage Practices Certificate (CBPDA), and update of Good Drug Bioavailability/Bioequivalence Practices Certificate (CBPBD/BE), when a corporate or commercial operation occurred.

Section I

About the Company Operating Permit (AFE) and the Special Authorization (AE) Art. 8th Companies must apply the update AFE and AE through change petition, cancellation, or concession, when the corporate transaction occurred.

Art. 9th When the corporate transaction results in a new legal entity or existing entity unregulated by the health surveillance, the adjustment shall be given by means of initial grant application of AFE and AE.

Art. 10th The cancellation request of the AFE and AE must be filed by the succeeded company, within thirty (30) days after publication of the cancellation Resolution and records of ownership transfer, if applicable.

Single paragraph. Only after the transfer of ownership of all the succeeded company records for one or more successor companies, there will be the cancellation of the AFE and AE of the succeeded company.

Art. 11 The petition to update data in the AFE or AE must be accompanied by the following documents:

I - duly completed and signed application form; and

II - statement of corporate transaction practiced, as provided in Annex I.

Section II

On the Good Practices Certification

Sub-section I

On the Good Manufacturing Practices Certification and Good Distribution and Storage Practices Certification

Art. 12th The successor company shall request update of its registration data for establishments involved in CBPF, or CBPDA if unchanged the technical and health characteristics previously examined, when the corporate or commercial operations occurred.

§1st The update of the heading of this article does not imply new certification, keeping unchanged the validity of the certificate issued prior to the operation.

§ 2nd The data update in CBPF will occur by production line and will only apply where the corporate or commercial transactions involve the whole of this production line.

§3rd In the case of corporate transactions that took place exclusively abroad, the updating referred in the heading of this article should be petitioned by the current company requesting the effective certification.

Art. 13th The request for data update in CBPF or CBPDA should be accompanied by the following documents:

I - duly completed and signed application form;

II - copy of current CBPDA or CBPF, in case where it has been previously published in operation;

III - statement of corporate or commercial transaction practiced, as provided in Annex;

IV - copy of the publication in the Federal Official Gazette (DOU) of the updated AFE or AE in case where the corporate transaction result in change or concession of AFE or AE; and

V - copy of current CBPF on behalf of the successor company, issued by the health authority of the country where is installed the production establishment or declaration of this authority attesting to the operation in the case of corporate transaction that occurred abroad.

Art. 14th The data update in CBPF or CBPDA does not apply to initial certification applications that are awaiting review or with analysis not yet completed.

§1st For the cases referred in the heading, the succeeded company will promote the addition of the application to update the documentation, for the instructions and further analysis of the petition in progress.

§2nd The succeeded company shall submit the documents referred to in art. 13 of this Resolution.

Sub-section II

On the Good Drug Bioavailability/Bioequivalence Practices Certificate

Art. 15th The successor company shall request update of the registration data for establishments involved in CBPBD/BE, if unchanged technical and health characteristics previously examined, when the corporate transaction occurred.

§1st The update referred at this article heading does not imply new certification, keeping unchanged the validity of the certificate issued prior to the operation.

§2nd In case of corporate transactions that took place exclusively abroad, the current company requesting the effective certification should petition the updating referred at this article heading.

Art. 16th The petition for data update in CBPBD/BE should be accompanied by the following documents:

I - duly completed and signed application form;

II - copy of current CBPBD/BE; and

III - statement of practiced corporate transaction, as provided in Annex I.

Art. 17th The update application in CBPBD/BE does not apply to initial certification applications which are awaiting review or with analysis not yet completed.

§1st For the cases referred in the heading, the succeeded company will promote the addition of the application to update the documentation, for the instructions and further analysis of the petition in progress.

§2nd The succeeded company shall submit the documents referred to in art. 16 of this Resolution.

CHAPTER III

ON THE OWNERSHIP TRANSFER

Section I

About Pesticides, their components and related

Art. 18th The successor company shall report to ANVISA the transfer of pesticide registration ownership, its components and the like, in the federal registering agency, according to the Decree No. 4074, of January 4th, 2002, within sixty (60) days, through the ownership change notification request, whenever occurred the corporate or commercial operations.

Art. 19th The application of the ownership change notification should be accompanied by the following documents:

I - duly completed and signed application form; and

II - copy of the DOU proving the ownership transfer in the federal registering agency

Section II

On the smoking products derivatives or not from Tobacco

Art. 20th Companies should update the data on the registration of smoking products with ANVISA, by means of ownership and deregistration transfer petition, whenever corporate or commercial operation occurred resulting in change of ownership of the records.

Art. 21st The ownership transfer and deregistration petitions should be concurrently docketed with ANVISA, respectively by the successor and succeeded companies within sixty (60) days.

§1st Petitions docketed outside the period referred in this article will be rejected by ANVISA.

§2nd The period referred to in the heading of this article shall be counted from the date of filing of the corporate act registered in the relevant trade association, or the conclusion of the contractual instrument of transfer of assets or a group of assets, as appropriate.

§3rd In case of Mercosur representative, the period referred to in the heading of this article shall be counted from the date on which formally is interrupted the contractual relationship between the company representative of Mercosur domiciled and record holder in Brazil and the company represented, record holder in another state part of Mercosur.

Art. 22nd The smoking products ownership transfer implies simultaneous publication in the Federal Official Gazette, of the new record and cancel the old registration, keeping unchanged the technical and health characteristics of the product and the expiration date of the record object of transfer.

Art. 23rd The request for registration of ownership transfer must be accompanied by the following documents:

I - duly completed and signed application form;

II - statement of corporate or commercial transaction practiced, as provided in Annex I;

III - proof of Enrollment and Registration Status with the Secretariat of the Federal Revenue of Brazil - Corporate Taxpayer's Registry (CNPJ); and

IV - copy of the Executive Declaratory Act (ADE) to grant the Special Registration of Manufacturer or Importer in case of product type cigarette or cigarillo, issued by the Federal Revenue Secretariat of Brazil, already referring to the successor company.

Art. 24th The corporate and commercial transactions involving the transfer of rights and obligations relating to registration applications that are awaiting review or with analysis not yet completed, do not characterize transfer of ownership.

§1st For the cases referred in the heading, the succeeded company will promote the addition of the application to update the documentation, for the instructions and further analysis of the petition in progress.

§2nd The company succeeded shall submit the documents referred to in art. 23 of this Resolution.

Section III

On the Drugs, Active Pharmaceutical Ingredients, Cosmetics, Sanitizing, Health Products and Food

Art. 25th Companies should update the data on the registration of products subject to sanitary surveillance, by means of ownership and deregistration transfer petition, whenever occurred corporate or commercial transactions involving the change of ownership of the product registration.

Art. 26th The ownership transfer and deregistration petitions should be concurrently filled with ANVISA, respectively by the successor and succeeded companies within 180 (one hundred and eighty) days.

§1st Petitions filed outside the period referred in this article heading will be rejected by ANVISA.

§2nd The period referred to in this article heading shall be counted from the date of filing of the corporate act registered in the relevant trade association, or the conclusion of the contractual instrument of transfer of assets or a group of assets, as appropriate.

§3rd In case of Mercosur representative, the period referred to in the heading of this article shall be counted from the date on which formally is interrupted the contractual relationship between the company representative of Mercosur domiciled and record holder in Brazil and the company represented, record holder in another state part of Mercosur.

Art. 27th Products subject to registration are equivalent to those subject to registration for ownership transfer of records.

Art. 28th Products subject to notification and registration free are not ownership transfer objects, the successor company should make a new notification or new regularization procedure, as appropriate.

Art. 29th The ownership transfer implies simultaneous publication in the Federal Official Gazette, of the new record and cancel the old registration, keeping unchanged the technical and health characteristics of the product and the expiration date of the record object of transfer.

Art. 30th The request for registration of ownership transfer must be accompanied by the following documents:

I - duly completed and signed application form;

II - proof of payment or exemption from the Health Surveillance Inspection Fee (TFVS) by Federal Tax Liability Payment Form (GRU);

III - statement of corporate or commercial transaction practiced, as provided in Annex I; and

IV - copy of the operating license or health permit issued by the competent body, duly updated after the corporate or commercial operations.

Art. 31st The corporate and commercial transactions involving the transfer of rights and obligations relating to registration applications that are awaiting review or with analysis not yet completed, do not characterize transfer of ownership.

§1st For the cases referred in the heading, the succeeded company will promote the addition of the application to update the documentation, for the instructions and further analysis of the petition in progress.

§2nd The company succeeded shall submit the documents referred to in art. 30 of this Resolution.

Art. 32nd The post-registration petitions already filled by the succeeded company and which are awaiting analysis or with analysis not yet completed, may be transferred to the successor company, upon presentation of the declaration of interest arranged in Annex I.

Single paragraph. The post-registration applications that are not in the declaration contained in Annex I will characterize withdrawal by the successor company and will be closed by ANVISA.

Art. 33rd The adjustments in the operating instructions texts, package inserts and labeling, arising from ownership transfer may be implemented after the approval of the ownership transfer request by ANVISA.

§1st The adjustments in the text instructions, package inserts and labeling dealt in the heading of this article are restricted to update of the registrant data.

§2nd In case of drugs, the successor company shall have a period of thirty (30) days after the entry into force of the cancellation and records transfer of ownership Resolutions, to apply for a change Notification of package insert text and labeling change Notification changes related to the characteristics of the new registration holder company.

Art. 34 As a result of the ownership transfer will be allowed to maintain different or distinct names for drugs with the same active ingredient(s).

CHAPTER IV

ON THE GLOBAL TRANSFER OF RESPONSIBILITY FOR CLINICAL TRIAL

Art. 35th The succeeded company must update the data on the clinical trial through a global transfer responsibility petition on clinical trial, wherever occurring the corporate or commercial operations.

Art. 36th The global transfer responsibility petition for clinical trial should be accompanied by the following documents:

I - duly completed and signed application form; and

II - statement of corporate or commercial transaction practiced, as provided in Annex I.

Art. 37th For requests of global transfer of responsibility for clinical trial, even those under responsibility of Clinical Research Organization (CRO), the Special Notice, Specific Special Notice or Document for Product under investigation Import will be issued in the name of the new responsible for the respective process.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

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Art. 38th Imports by the successor company, based on the succeeded company AFE, will be allowed until occurs ANVISA's decision on the regularization of the company, provided that observing the terms for protocol established by this resolution.

Single paragraph. The importer must present a certified copy of the statement of operation practiced for the health authority of the place of clearance, as documentary evidence of the corporate or commercial operations, as provided in Annex I.

Art. 39th The responsibility for the product and any remaining stock of finished products will be on the successor company, including import purposes in cases of ownership transfer registration.

§1st Until the ownership transfer occurs of the products registrations with ANVISA, imports made by the successor company shall be accompanied by the succeeded company statement, a signatory of the product regularization petition with ANVISA authorizing imports.

§2nd The provisions in the heading of this article does not exclude joint liability of the succeeded company to the health surveillance organs and entities for acts committed prior to the corporate or commercial operations.

Art. 40th The remaining stock of finished products object of ownership transfer may be regularly imported or marketed by the new record holder, provided it has been produced before the entry into force of the cancellation of resolutions and records of ownership transfer.

Single paragraph. Companies will have a maximum of 180 (one hundred and eighty) days after the entry into force of the cancellation of resolutions and records of ownership transfer, for remaining stock depletion of finished products.

Art. 41st The use and depletion of any remaining inventory packages with text or outdated labeling information for new batches produced after the entry into force of the cancellation and records of ownership transfer Resolutions will not be allowed.

Art. 42nd The provisions contained in articles 39, 40 and 41 do not apply to pesticide products, their components and the like, because they are subject to the rules established by the federal registering agency.

Art. 43rd The product registration ownership transfer requests due to corporate transactions, filed before the effective date of this resolution will be analyzed according to the current Resolution at the time of protocol.

Art. 44th Deadlines for protocol established by this resolution will focus on the product registration of ownership transfer requests due to commercial operations prior to the effective date of this Resolution.

Single paragraph. In cases classified in the heading, companies will be able to docketing with ANVISA within 180 (one hundred and eighty) days from the effective date of this Resolution, concurrent requests for ownership transfer and cancellation of product registration, as needed.

Art. 45th The companies involved in corporate and commercial operations should provide information and submit additional documents, when requested by ANVISA.

Art. 46th ANVISA may, at any time, request a copy of the filing certificate of the registered corporate act, in case of corporate transaction, or contractual instrument of transfer of assets or a group of assets, in the event of commercial operation.

Art. 47th Unless otherwise specified, the cancellation and registration of ownership transfer Resolutions of products subject to sanitary surveillance pursuant to this Resolution begin to take effect ninety (90) days after its publication.

Art. 48th The delay, omission or providing false or misleading information, in violation of the provisions of this Resolution constitutes a sanitary infraction, subjecting the violator to the penalties provided in Law No. 6437 of August 20th, 1977, subject to civil and criminal liability provided in the existing applicable rules.

Art. 49th The Collegiate Board of Directors Resolution - RDC No. 22 of June 17th, 2010, Normative Ruling No. 03 of May 3rd, 2012, and item 4, Chapter III of RDC Amendment No. 323, of November 10th, 2003 are hereby revoked.

Art. 50th This Resolution shall enter into force within 120 (one hundred twenty) days from the date of its publication.

JARBAS BARBOSA DA SILVA JÚNIOR

ANNEX I

STATEMENT OF REGISTRATION DATA UPDATING RELATED TO COMPANIES' OPERATION AND CERTIFICATION, GLOBAL TRANSFER OF RESPONSIBILITY FOR CLINICAL TRIAL AND PRODUCTS REGISTRATION OWNERSHIP TRANSFER SUBJECT TO SANITARY SURVEILLANCE.

For the purpose of updating of registration data for companies' operation and certification, global transfer of responsibility for clinical trial and products registration ownership transfer subject to sanitary surveillance, the **SUCCEEDED COMPANY** _____, registered at the CNPJ [Corporate Taxpayer's Registry] under No. _____, with headquarters at _____, city _____ State _____, legally represented by _____, ID No. _____, issued by the agency _____, CPF [Individual Taxpayer's Registry] No. _____, and the **SUCCESSOR COMPANY** _____, registered at the CNPJ under No. _____, with headquarters at _____, city _____ State _____, legally represented by _____, ID No. _____, issued by the agency _____, CPF No. _____, **DECLARE UNDER PENALTY OF LAW**, before ANVISA, for purposes of the provisions of Resolution RDC No. 102, of August 24th, 2016, that they performed the operation _____ (corporate or commercial) called _____ (merger, spin-off or incorporation, in case of corporate operation, or sale of assets or a group of assets, in case of commercial operation), as present at _____ (of filing certificate of corporate act registered in case of corporate transaction, or contractual instrument of transfer of assets or a group of assets, in the event of commercial operation), issued by _____ (identification of the board of trade, in case of corporate operation, or by the succeeded company to celebrate the transfer, in case of commercial operation) on _____ of _____.

(FILL OUT IN CASE OF AFE AND AE DATA UPDATE):

The successor company DECLARES that the petition is related to the branches establishments of the succeeded company listed below:

CNPJ	Corporate Name	Address

(FILL OUT IN CASE OF GOOD MANUFACTURING PRACTICES CERTIFICATE (CBPF) OR DISTRIBUTION AND STORAGE (CBPDA) UPDATE):
 The successor and succeeded companies DECLARE that the petition is related with the production line informed below:

Production line (according to current legislation)	Products manufactured in the production line		
The successor company DECLARES that is interested in the analysis of certification petitions filled by the succeeded company which analysis has not been completed by ANVISA as per the following list:			
Filling date	Expedient Number	Subject	Products manufactured at the productive line

(FILL OUT IN CASE OF GOOD DRUG BIOAVAILABILITY/ BIOEQUIVALENCE PRACTICES CERTIFICATE (CBPBD/BE) UPDATE):
 The successor company DECLARES that is interested in the analysis of certification petitions filled by the succeeded company which analysis has not been completed by ANVISA as per the following list:

Filling date	Expedient Number	Subject

(FILL OUT IN CASE OF GLOBAL TRANSFER OF RESPONSIBILITY FOR CLINICAL TRIAL):
 The succeeded company DECLARES that in case of global transfer of responsibility for DDCM or DICD processes, transfers the responsibility for the following processes of clinical trials specific dossiers to the successor company:

Filling date	Expedient Number	Subject

The succeeded company DECLARES that the clinical trials processes not mentioned above will be kept under responsibility of the person in charge of the initial submission to ANVISA. This status does not apply to situations involved clinical trials specific dossiers, clinical trial notification, programs of expanded access, compassionate use and post study drug supply.

(FILL OUT IN CASE OF OWNERSHIP TRANSFER OF PRODUCT REGISTRATION):
 The successor company DECLARES that is interested in the analysis of post registration petitions filled by the succeeded company which analysis has not been completed by ANVISA as per the following list:

Filling date	Expedient Number	Subject

The successor company DECLARES that it gives up the post-registration applications are not on the list above, and is aware that these petitions will be closed by ANVISA, pursuant to Single paragraph of art. 32 of the RDC Resolution No. 102, of August 24th, 2016.

The cited companies DECLARE under penalties of Law, through its legal and technical representatives, that there was no change of sanitary technical characteristics previously approved by ANVISA and DECLARE that no change in technical and health characteristics will be held until there is authorization, approval or certification of activity, according to the formal acts issued by ANVISA.

The cited companies DECLARE UNDER THE PENALTIES OF LAW, through its legal and technical representatives, that the information given above are the expression of truth and both assume joint responsibility for its accuracy.

Technical person in charge from the succeeded company

Signature _____
CPF: _____

_____, _____, of _____

Technical person in charge from the successor company

Signature _____
CPF: _____

_____, _____, of _____

Technical person in charge from the succeeded company

Signature _____
CPF: _____

_____, _____, of _____

Technical person in charge from the successor company

Signature _____
CPF: _____

_____, _____, of _____

ABRACRO

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ANNEX II

STATEMENT OF CORPORATE OPERATION EXECUTED ABROAD

For the purpose of updating of registration data for companies' operation the **REQUESTING COMPANY** _____, registered at the CNPJ [*Corporate Taxpayer's Registry*] under No. _____, with headquarters at _____, city _____ State _____, legally represented by _____, ID No. _____, issued by the agency _____, CPF [*Individual Taxpayer's Registry*] No. _____, DECLARES before ANVISA, for purposes of the provisions of Resolution RDC No. 102, of August 24th, 2016, that the **SUCCEDED COMPANY** _____, with headquarters at _____, city _____ State _____, and the **SUCCESSOR COMPANY** _____, with headquarters at _____, city _____ State _____, performed corporate operation abroad in _____.

The requesting company DECLARES under penalties of Law, through its legal representative, that there was no change of sanitary technical characteristics previously approved by ANVISA and DECLARES that no change in technical and health characteristics will be held until there is authorization, approval or certification of activity, according to the formal acts issued by ANVISA.

The requesting company DECLARES UNDER PENALTIES OF LAW, through its legal representative, that the information given above are the expression of truth and assumes responsibility for its accuracy.

Legal person in charge from the requesting company

Signature _____

CPF: _____

_____, _____, _____