COLLEGIATE BOARD RESOLUTION – RDC NO. 102 OF 24 AUGUST 2016

(Published in the Federal Official Gazette no. 164 of 25 August 2016)

Provides for the procedures to transfer the marketing authorization for products subject to health surveillance, global transfer of responsibility for clinical trials, and update of registration data related to the operation and certification of companies, as a result of corporate or commercial operations.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under items III and IV of Article 15 and items III and IV of Article 7 of Law no. 9,782 of 26 January 1999, and considering the provisions in Article 53, item V, and paragraphs 1 and 3 of Anvisa Regulation approved pursuant to Annex I of Collegiate Board Resolution – RDC no. 61 of 3 February 2016, as decided upon in a meeting held on 12 July 2016, adopts the following Collegiate Board Resolution and I, Director-President, determine its publication.

CHAPTER I

GENERAL PROVISIONS

Article 1. This Resolution is applied to corporate and commercial operations between companies that perform the activities provided for in the federal health legislation, and which result in the need to update the registration data related to the operation and certification of companies, global transfer of responsibility for clinical trials and transfer of marketing authorization for products subject to health surveillance.

Sole Paragraph. This Resolution also covers the cases of operations performed abroad that require update under Anvisa.

Article 2. The procedures established in this Resolution apply exclusively to cases where the technical and health conditions and characteristics of the companies, products, and clinical trials are maintained.

Article 3. The procedures established in this Resolution do not apply to the alterations in company name not related to the operations referred to in Article 1 hereof, which are subject to the specific regulations in force.

Article 4. For the purposes of this Resolution, the following definitions shall be adopted:

I – Technical and health characteristics: regular conditions of the product, company, or clinical trial at ANVISA, immediately before the corporate or commercial operation;

II – Divestiture: corporate operation through which a legal entity transfers parts of its property to one or more legal entities established for this purpose, or already existent, extinguishing the

demerged company if all its assets are transferred, or dividing the capital if the transfer is partial;

III – Succeeded company: legal entity that transfers to the successor company the rights and obligations on the product object of marketing authorization transfer, the establishment, or the responsibility for clinical trials, as a result of corporate or commercial operations;

IV – Successor company: legal entity that now has the rights and obligations on the product object of marketing authorization transfer, the establishment, or the responsibility for clinical trials, as a result of corporate or commercial operations;

V – Amalgamation: corporate operation through which two or more legal entities are merged to create a third one, succeeding them in all rights and obligations;

VI – Merger: corporate operation through which one or more legal entities are absorbed by another one, succeeding them in all rights and obligations;

~~VII – Commercial operation: operation between companies resulting in the sale of assets or group of assets, without the occurrence of any corporate operation between the companies involved;~~

VII – Commercial operation: operation between companies resulting in the transfer of assets or group of assets, without the occurrence of any corporate operation between the companies involved; **(Wording given by Resolution – RDC no. 233, of 20 June 2018)**

VIII – Corporate operation: corporate action involving the divestiture, amalgamation, or merger pursuant to Law no. 10,406, of 10 January 2002 and, in a subsidiary manner, Law no. 6,404, of 15 December 1976;

IX – Mercosur representative: company located in the Receiving State Party [*Estado Parte Receptor (EPR)*, in Portuguese], which is contracted to represent a marketing authorization holder in the Producing State Party [*Estado Parte Produtor (EPP)*, in Portuguese] and takes the legal and technical responsibility in the EPR;

X – Global transfer of responsibility for clinical trial: modification characterized by the alteration in the applicant for clinical trial dossiers, notification of clinical trial, dossiers of clinical development of medicinal products (DDCM, in Portuguese), dossiers of clinical investigation of medical devices (DICD, in Portuguese), expanded access programs, compassionate use programs, and supply of post-study medicinal product, in cases of corporate or commercial operations, without any alteration in technical and health characteristics contained in the Specific Special Notification [*Comunicado Especial Específico (CEE)*, in Portuguese], Document for the Import of Product under Investigation or Special Notification [*Comunicado Especial (CE)*, in Portuguese], object of alteration;

XI – Transfer of marketing authorization holder: modification characterized by the alteration in the holder of marketing authorization for products subject to health surveillance, in case of corporate or commercial operations, without any alteration in technical and health characteristics in the marketing authorization for the product object of transfer.

Article 5. The companies must submit an application for update of registration data related to the operation and certification of companies, global transfer of responsibility for clinical trial, and transfer of marketing authorization for products subject to health surveillance, as a result of corporate or commercial operations, in the terms of this Resolution.

Sole Paragraph. In case of successive corporate or commercial operations, an application for each operation must be submitted.

Article 6. As of the execution of corporate or commercial operation, the successor company obtains the rights and obligations from the succeeded company, including the compliance with deadlines and rules for adjustment to the health legislation and any restrictive measures applicable to the circulation of products.

CHAPTER II

UPDATE OF REGISTRATION DATA

Article 7. Companies must submit to Anvisa the applications for alteration, granting, and/ or cancellation of Company's Operation Permit [*Autorização de Funcionamento de Empresa (AFE)*, in Portuguese] and Special Operation Permit [*Autorização Especial (AE)*, in Portuguese], update of the Good Manufacturing Practices Certificate (CBPF, in Portuguese) or the Good Distribution and Storage Practices Certificate (CBPDA, in Portuguese), and update of the Good Practices of Bioavailability/ Bioequivalence of Medicinal Products Certificate (CBPBD/BE, in Portuguese), whenever there is a corporate or commercial operation.

Section I

Company's Operation Permit (AFE) and Special Operation Permit (AE)

Article 8. Companies must request the update of the Operation Permit and the Special Operation Permit through the submission of an application for alteration, cancellation, or granting, whenever there is a corporate operation.

Article 9. If the corporate operation results in a new legal entity, or already existing legal entity not registered at the health surveillance agency, the registration must be carried out through the submission of an application for the initial grant of Operation Permit and Special Operation Permit.

Article 10. The application for cancellation of Operation Permit and Special Operation Permit must be submitted by the succeeded company within thirty (30) days counting from the publication of the Resolution of cancellation and of marketing authorization transfer, when applicable.

Sole Paragraph. The cancellation of the Operation Permit and Special Operation Permit of the succeeded company shall be carried out only after the transfer of all marketing authorizations of the succeeded company to one or more successor companies.

Article 11. The application for update of data in the Operation Permit or Special Operation Permit must be submitted including the following documents:

I – application form duly completed and signed; and

II – statement of the corporate or commercial operation performed, as provided for in Annex I.

Section II

Good Practices Certification

Subsection I

Good Manufacturing Practices Certification and Good Distribution and Storage Practices Certification

Article 12. The successor company must request the update of registration data of the establishments involved in the GMP Certificate, or in the Good Distribution and Storage Practices Certificate, provided that the previously verified technical and health characteristics remain unaltered, whenever there is a corporate or commercial operation.

Paragraph 1. The update referred to in the caption of this Article does not imply in a new certification, and the expiration date of the certificate issued prior to the operation remains unchanged.

Paragraph 2. The update of data in the GMP Certificate shall occur per production line and shall be applied only in the cases where the corporate and commercial operations involve this entire production line.

Paragraph 3. In case of corporate operations occurred exclusively abroad, the application for the update referred to in the caption of this Article must be submitted by the current company applying for the certification in force.

Article 13. The application for the update of data in the GMP Certificate, or in the Good Distribution and Storage Practices Certificate, must be submitted with the following documents:

I – application form duly completed and signed;

II – copy of the GMP Certificate or Good Distribution and Storage Practices Certificate in force, in case this has been published prior to the operation;

III – declaration of the corporate or commercial operation carried out, as provided for in the Annexes;

IV – copy of the publication of the updated Operation Permit or Special Operation Permit in the Federal Official Gazette, in case the corporate operation results in alteration or granting of Operation Permit or Special Operation Permit; and

V – copy of the GMP Certificate in force in the name of the successor company, issued by the health authority of the country where the manufacturing establishment is installed or declaration by this authority certifying the operation, in case of corporate operation performed abroad.

Article 14. The update of data in GMP Certificate or Good Distribution and Storage Practices Certificate is not applicable to applications for initial certification that are waiting for analysis, or with uncompleted analysis.

Paragraph 1. For the cases provided for in the caption of this article, the succeeded company must make the amendment of the application for documentation update, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company must submit the documents provided for in Article 13 of this Resolution.

Subsection II

Good Practices of Bioavailability/ Bioequivalence of Medicinal Products Certificate

Article 15. The successor company must request the update of registration data of the establishments involved in the GPBA/BE Certificate, provided that the previously verified technical and health characteristics remain unaltered, whenever there is a corporate or commercial operation.

Paragraph 1. The update provided for in the caption of this Article does not imply in a new certification, and the expiration date of the certificate issued prior to the operation remains unchanged.

Paragraph 2. In case of corporate operations occurred exclusively abroad, the application for the update referred to in the caption of this Article must be submitted by the current company applying for the certification in force.

Article 16. The application for the update of data in the GPBA/BE Certificate must be submitted with the following documents:

I – application form duly completed and signed;

II – copy of the GPBA/BE Certificate in force; and

III – declaration of the corporate operation carried out, as provided for in Annex I.

Article 17. The application for the update of data in the GPBA/BE Certificate is not applicable to applications for initial certification that are waiting for analysis, or with uncompleted analysis.

Paragraph 1. For the cases provided for in the caption of this article, the succeeded company must make the amendment of the application for documentation update, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company must submit the documents provided for in Article 16 of this Resolution.

CHAPTER III

MARKETING AUTHORIZATION TRANSFER

Section I

Pesticides, their Components, and Related Products

Article 18. The successor company must notify Anvisa of the transfer of marketing authorization for pesticides, their components, and related products in the federal registering body, in accordance with the provisions established by Decree no. 4,074 of 4 January 2002,

within sixty (60) days through submitting an application for the notification of alteration in marketing authorization, whenever there is a corporate or commercial operation.

Article 19. The application for the notification of alteration in marketing authorization must be submitted with the following documents:

I – application form duly completed and signed; and

II – copy of the Federal Official Gazette confirming the transfer of marketing authorization in the federal registering body.

Section II

Smoking Products Derived or Not from Tobacco

Article 20. Companies must update the data related to the marketing authorization of smoking products at Anvisa through submitting an application for the transfer of marketing authorization and cancellation of marketing authorization, whenever there is a corporate or commercial operation leading to the alteration in marketing authorization.

Article 21. Applications for the transfer of marketing authorization and cancellation of marketing authorization must be submitted simultaneously to Anvisa by the successor and succeeded companies, respectively, within sixty (60) days.

Paragraph 1. Applications submitted after the deadline provided for in the caption of this Article shall be rejected by ANVISA.

Paragraph 2. The deadline referred to in the caption of this Article shall be counted from the date of filing the corporate action registered in the competent commercial registry, or of signing the contractual instrument of transfer of assets or group of assets, as appropriate.

Paragraph 3. In case of Mercosur representative, the deadline provided for in the caption of this Article shall be counted from the date when the contractual relation is formally interrupted between the domestic Mercosur representative company and marketing authorization holder in Brazil and the represented company, marketing authorization holder in another Mercosur State Party.

Article 22. The transfer of marketing authorization for smoking products entails the simultaneous publication of the new marketing authorization and cancellation of the old marketing authorization in the Federal Official Gazette. The technical and health characteristics of the product and the expiration date of the marketing authorization object of transfer shall remain unchanged.

Article 23. The application for the transfer of marketing authorization must be submitted with the following documents:

I – application form duly completed and signed;

II – declaration of the corporate or commercial operation carried out, as provided for in Annex I;

III – proof of registration and registration situation at the Department of Federal Revenue of Brazil – Brazilian Registry of Legal Entities (CNPJ); and

IV – copy of the Executive Declaratory Act (ADE, in Portuguese) that grants the Special Registration of Manufacturer or Importer, in case of cigarette or cigarillo, issued by the Department of Federal Revenue of Brazil, already related to the successor company.

Article 24. Corporate or commercial operations involving the transfer of rights and obligations related to applications for marketing authorization that are waiting for analysis, or with uncompleted analysis, do not characterize transfer of title.

Paragraph 1. For the cases provided for in the caption of this article, the succeeded company must make the amendment of the application for documentation update, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company must submit the documents provided for in Article 23 of this Resolution.

Section III

Medicinal Products, Active Pharmaceutical Ingredients, Cosmetics, Sanitizing Products, Health Products, and Food

Article 25. Companies must update the data related to the marketing authorization of products subject to health surveillance through submitting an application for transfer of marketing authorization and cancellation of marketing authorization, whenever there is a corporate or commercial operation leading to the alteration in the marketing authorization for products.

Article 26. Applications for the transfer of marketing authorization and cancellation of marketing authorization must be submitted simultaneously to Anvisa by the successor and succeeded companies, respectively, within one hundred and eighty (180) days.

Paragraph 1. Applications submitted after the deadline provided for in the caption of this Article shall be rejected by Anvisa.

Paragraph 2. The deadline provided for in the caption of this Article shall be counted from the date of filing the corporate action registered in the competent commercial registry, or of signing the contractual instrument of transfer of assets or group of assets, as appropriate.

Paragraph 3. In case of Mercosur representative, the deadline provided for in the caption of this Article shall be counted from the date when the contractual relation is formally interrupted between the domestic Mercosur representative company and marketing authorization holder in Brazil and the represented company, marketing authorization holder in another Mercosur State Party.

Article 27. Products subject to register are equivalent to those subject to marketing authorization for the purposes of transfer of marketing authorization title.

Article 28. Products subject to notification and those exempt from marketing authorization shall not be object of transfer of title, and the company must issue a new notification or new regularization procedure, as appropriate.

Article 29. The transfer of marketing authorization entails the simultaneous publication of the new marketing authorization number and cancellation of the old marketing authorization

number in the Federal Official Gazette. The characteristics of the product and expiration date of the marketing authorization object of transfer shall remain unchanged.

Article 30. The application for transfer of marketing authorization must be submitted with the following documents:

I – application form duly completed and signed;

II – payment proof of the Health Surveillance Inspection Fee (TFVS, in Portuguese) through the corresponding Brazilian Federal Tax Collection Form (GRU, in Portuguese), or exemption from such payment;

III – declaration of the corporate or commercial operation carried out, as provided for in Annex I; and

IV – copy of the Operation Permit or Health Permit issued by the competent body, properly updated after the corporate or commercial operation.

Article 31. Corporate or commercial operations involving the transfer of rights and obligations related to applications for marketing authorization that are waiting for analysis, or with uncompleted analysis, do not characterize transfer of title.

Paragraph 1. For the cases provided for in the caption of this article, the succeeded company must make the amendment of the application for documentation update, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company must submit the documents provided for in Article 30 of this Resolution.

Article 32. Post-marketing authorization applications already submitted by the succeeded company that are waiting for analysis, or with uncompleted analysis, may be transferred to the successor company, through the submission of the declaration of interest provided for in Annex I.

Sole Paragraph. Post-marketing authorization applications that do not have the declaration provided for in Annex I shall characterize a waiver by the successor company and those applications shall be closed by Anvisa.

Article 33. Adjustments in the texts of instructions for use, package inserts, and labeling, as a result of transfer of title, may be implemented after the approval of the application for transfer of title by Anvisa.

Paragraph 1. Adjustments in the texts of instructions for use, package inserts, and labeling provided for in the caption of this Article shall be restricted to the update of marketing authorization holder data.

Paragraph 2. In case of medicinal products, the successor company shall have thirty (30) days, counting from entry into force of the Resolutions of cancellation and transfer of marketing authorization, to apply for Notification of alteration in the text of package inserts and Notification of alteration of labeling related to the characteristics of the new marketing authorization holder.

Article 34. The maintenance of different or distinct names for medicinal products with the same active ingredient(s) shall be permitted as a result of the transfer of title.

CHAPTER IV

Global Transfer of Responsibility for Clinical Trial

Article 35. The succeeded company must update the data related to the clinical trial through submitting an application for the global transfer of responsibility for clinical trial, whenever there is a corporate or commercial operation.

Article 36. The application for the global transfer of responsibility for clinical trial must be submitted with the following documents:

I – application form duly completed and signed; and

II – declaration of the corporate or commercial operation carried out, as provided for in Annex I.

Article 37. In case of applications for the global transfer of responsibility for clinical trial, even the clinical trials under the responsibility of the Representative Organization of Clinical Research (*Organização Representativa de Pesquisa Clínica* – ORPC, in Portuguese), the Special Notification, Specific Special Notification, or Document for the Import of Product under Investigation shall be issued on behalf of the new entity responsible for the respective process.

CHAPTER V

Final and Transitional Provisions

Article 38. Imports carried out by the succeeded company, based on the Operation Permit of the successor company, shall be permitted until Anvisa publishes the decision on the regularization of the company, provided that the deadlines for the submission established by this Resolution are observed.

~~Sole Paragraph. The importing company must present a certified copy of the declaration of operation carried out to the health authority at the clearance point, such as documentary evidence of the corporate or commercial operation, as provided for in Annex I.~~

Sole Paragraph. The importing company must present a copy of the declaration of operation carried out to the health authority at the clearance point, such as documentary evidence of the corporate or commercial operation, as provided for in Annex I. **(Wording given by Resolution – RDC no. 438 of 6 November 2020)**

Article 39. The successor company shall be responsible for the product and any remaining stock of finished products, including for import purposes, in cases of transfer of marketing authorization.

Paragraph 1. Until the transfer of product marketing authorization at Anvisa is approved, the imports carried out by the successor company must be accompanied by the declaration of the succeeded company, signatory of the application for regularization of the product at ANVISA, authorizing the import.

Paragraph 2. The provisions in the caption of this Article do not exempt the joint liability of the succeeded company before health surveillance bodies and entities for the actions performed prior to the corporate or commercial operation.

Article 40. The remaining stock of finished products object of marketing authorization transfer may be regularly imported or commercialized by the new marketing authorization holder, provided that these products have been manufactured before the entry into force of the Resolutions of cancellation and transfer of marketing authorization.

Sole Paragraph. Companies shall have a maximum of one-hundred and eighty (180) days, counting from the entry into force of the Resolutions of cancellation and transfer of marketing authorization, to sell out the remaining stock of finished products.

Article 41. The use and depletion of any remaining stock of packaging with outdated labeling wording or information shall not be allowed for new batches produced after the entry into force of the Resolutions of cancellation and transfer of marketing authorization.

Article 42. The provisions in Articles 39, 40, and 41 do not apply to pesticides, their components and related products, because they are subject to the rules established by the federal registering body.

Article 43. Applications for the transfer of marketing authorization as a result of corporate operations, submitted before the effective date of this Resolution, shall be analyzed in accordance with the Resolution in force at the time of submission.

Article 44. The submission deadlines established by this Resolution shall not be imposed on the applications for the transfer of marketing authorization as a result of commercial operations carried out before the entry into force of this Resolution.

Sole Paragraph. In the cases provided for in the caption of this Article, companies may submit to Anvisa the corresponding applications for the transfer of title and cancellation of product marketing authorization within one-hundred and eighty (180) days, counting from the entry into force of this Resolution, as appropriate.

Article 44-A Companies that carried out corporate operations between 12 July 2016 and 25 August 2016, may submit to Anvisa, in the terms of this Resolution, the corresponding applications for the transfer of title and cancellation of product marketing authorization, as appropriate, until 21 February 2017. **(Wording included by Resolution – RDC no. 118 of 26 October 2016)**

Article 45. Companies involved in corporate and commercial operations must provide information and submit additional documents, whenever required by Anvisa.

Article 46. At any time, Anvisa may request the copy of the certificate of filing of corporate action registered in the competent commercial registry, in case of corporate operation, or the contractual instrument of transfer of assets or group of assets, in case of commercial operation.

Article 47. Except as otherwise provided for, the Resolutions of cancellation and transfer of marketing authorization for products subject to health surveillance referred to in this Resolution shall come into force ninety (90) days after their publication.

Article 48. The delay, omission, or provision of false or misleading information in disagreement with the provisions in this Resolution shall constitute a health violation, and the offender is subject to the penalties provided in Law no. 6,437 of 20 August 1977, without prejudice to the civil and criminal liabilities provided for in the applicable legislation in force.

Article 49. Collegiate Board Resolution – RDC no. 22 of 17 June 2010, Normative Instruction no. 03 of 3 May 2012, and item 4, Chapter III of the Annex of RDC no. 323 of 10 November 2003 are hereby revoked.

Article 50. This Resolution shall come into force one-hundred and twenty (120) days after its publication.

JARBAS BARBOSA DA SILVA JÚNIOR

ANNEX I

DECLARATION OF UPDATE OF REGISTRATION DATA RELATED TO THE OPERATION AND CERTIFICATION OF COMPANIES, GLOBAL TRANSFER OF RESPONSIBILITY FOR CLINICAL TRIAL AND TRANSFER OF MARKETING AUTHORIZATION FOR PRODUCTS SUBJECT TO HEALTH SURVEILLANCE

For the purposes of updating the registration data related to the operation and certification of companies, global transfer of responsibility for clinical trial and transfer of marketing authorization for products subject to health surveillance, the **SUCCEEDED COMPANY** _____, registered with the CNPJ (Brazilian Registry of Legal Entities) under no. _____ , with a primary place of business at _____, city _____, State _____, legally represented by _____, ID no. _____, issued by _____, CPF (Brazilian Individual Taxpayer Registration) no. _____, and the **SUCCESSOR COMPANY** _____, registered with the CNPJ (Brazilian Registry of Legal Entities) under no. _____, with a primary place of business at _____, city _____, State _____, legally represented by _____, ID no. _____ , issued by _____, CPF (Brazilian Individual Taxpayer Registration) no. _____ **DECLARE UNDER THE PENALTY OF LAW**, before Anvisa, for the purposes of the provisions in Resolution – RDC no. 102 of 24 August 2016, that they carried out the (corporate or commercial) operation _____ named _____ (amalgamation, divestiture or merger, in case of corporate operation, or sale of assets or group of assets, in case of commercial operation), as contained in _____ (the certificate of filing of corporate action registered in the competent commercial registry, in case of corporate operation, or the contractual instrument of transfer of assets or group of assets, in case of commercial operation), issued by _____ (identification of the commercial registry, in case of corporate operation, or by the succeeded company for signing the transfer in case of commercial operation) on _____ (day/ month/ year).

(COMPLETE THIS TABLE IN CASE OF UPDATE OF DATA OF OPERATION PERMIT AND SPECIAL OPERATION PERMIT):

The successor company DECLARES that the application is related to the subsidiaries of the succeeded company listed below:

CNPJ (Brazilian Registry of Legal Entities)	Company name	Address

[COMPLETE THIS TABLE IN CASE OF UPDATE OF CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) OR GOOD DISTRIBUTION AND STORAGE PRACTICES (GDSP)]:

The successor and succeeded companies DECLARE that the application is related to the production line informed below:

Production line (according to the legislation in force)	Products manufactured in the production line

The successor company DECLARES that it is interested in the analysis of applications for certifications submitted by the succeeded company, and which has not had their analysis yet completed by Anvisa, according to the list below:

Submission date	Number of Protocol	Subject	Products manufactured in the production line

[COMPLETE THIS TABLE IN CASE OF UPDATE OF CERTIFICATE OF GOOD PRACTICES OF BIOAVAILABILITY/BIOEQUIVALENCE OF MEDICINAL PRODUCTS (GPBA/BE)]:

The successor company DECLARES that it is interested in the analysis of applications for certifications submitted by the succeeded company, and which has not had their analysis yet completed by Anvisa, according to the list below:

Submission date	Number of Protocol	Subject

(COMPLETE THIS TABLE IN CASE OF GLOBAL TRANSFER OF RESPONSIBILITY FOR CLINICAL TRIAL):

The succeeded company DECLARES that, in case of global transfer of responsibility for dossiers of clinical development of medicinal products (DDCM, in Portuguese) or dossiers of clinical investigation of medical devices (DICD, in Portuguese), the company transfers the responsibility for the following applications of specific dossiers of clinical trials to the successor company:

Submission date	Number of Protocol	Subject

The succeeded company DECLARES that the clinical trial processes not listed above will remain under the responsibility of the person responsible for the initial submission to Anvisa.
This table is not applicable to situations involving specific dossiers of clinical trials, clinical trial notification, expanded access programs, compassionate use programs, and post-study supply of medicinal product.

(COMPLETE THIS TABLE IN CASE OF TRANSFER OF PRODUCT MARKETING AUTHORIZATION):

The successor company DECLARES that it is interested in the analysis of post-marketing authorization applications submitted by the succeeded company, and which has not had their analysis yet completed by Anvisa, according to the list below:

Submission date	Number of Protocol	Subject

The successor company DECLARES the withdrawal from post-marketing authorization applications that are not listed above and is aware that such applications will be closed by Anvisa, as provided for in Resolution – RDC no. 102, of 24 August 2016, Article 32, Sole Paragraph.

The companies abovementioned DECLARE under the penalty of law, through their legal and technical representatives, that there was no alteration in the technical and health characteristics previously approved by Anvisa and also DECLARE that no alteration in technical and health characteristics will be carried out until there is an authorization, approval, or certification of the activity, according to the applicable formal acts issued by Anvisa.

The companies abovementioned DECLARE UNDER THE PENALTY OF LAW, through their legal and technical representatives, that the information provided above is true and both companies take joint and liability for its accuracy.

~~Technical Responsible Officer of the succeeded company~~

~~Signature:~~

~~CPF:~~

~~_____~~

~~(day/month/year)~~

~~Technical Responsible Officer of the successor company~~

~~Signature:~~

~~CPF:~~

~~_____~~

~~(day/month/year)~~

Legal Responsible Officer of the succeeded company

Signature:

CPF:

_____

(day/month/year)

Legal Responsible Officer of the successor company

Signature:

CPF:

_____

(day/month/year)

(Rectified in the Federal Official Gazette no. 165 of 26 August 2016)

Technical Responsible Officer of the succeeded company

Signature:

CPF:

_____

(day/month/year)

Technical Responsible Officer of the successor company

Signature:

CPF:

_____

(day/month/year)

ANNEX II

DECLARATION OF CORPORATE OPERATION CARRIED OUT ABROAD

For the purposes of updating the registration data related to the operation of companies, the **APPLICANT COMPANY** _____, registered with the CNPJ (Brazilian Registry of Legal Entities) under no. _____, with a primary place of business at _____, city _____, State _____, legally represented by _____, ID no. _____, issued by _____, CPF (Brazilian Individual Taxpayer Registration) no. _____, DECLARES before Anvisa, for the purposes of the provisions in Resolution – RDC no. 102, of 24 August 2016, that the **SUCCEEDED COMPANY** _____, with a primary place of business at _____, city _____, State _____, Country _____, and the **SUCCESSOR COMPANY** _____, with a primary place of business at _____, city _____, State _____, Country _____performed a corporate operation abroad on _____ (day/ month/ year).

The applicant company DECLARES under the penalty of law, through its legal representative, that there was no alteration in the technical and health characteristics previously approved by Anvisa, and DECLARES that no alteration in technical and health characteristics will be carried out until there is an authorization, approval, or certification of the activity, according to the applicable formal acts issued by Anvisa.

The applicant company DECLARES UNDER THE PENALTY OF LAW, through its legal representative, that the information provided is true and the company takes joint liability for its accuracy.

Legal Responsible Officer of the applicant company

Signature: _____

CPF: _____

_____

(day/ month/ year)