

## Definition of Regulatory Filings

SHARE

CITE TERM

**Regulatory Filings** means as to any Performance Period, filings submitted to an Approval Authority with respect to a Product for which the Company is pursuing Product Approval.

BASED ON 70 DOCUMENTS

**Regulatory Filings** means, with respect to a Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, any NDA, any submission to a regulatory advisory board, any marketing authorization application (including any MAA), any BLA (biologics license application) and any supplement or amendment thereto.

BASED ON 46 DOCUMENTS

**Regulatory Filings** means all reports, offering circulars, proxy statements, registration statements and all similar documents filed, or required to be filed, pursuant to applicable state or federal law.

BASED ON 33 DOCUMENTS

## Examples of Regulatory Filings in a sentence

Celgene shall have responsibility for, and shall prepare, all **Regulatory Filings** and related submissions with respect to such Celgene Development Compound(s).

Upon request, Globelimmune will provide the JRC and Celgene with copies of all **Regulatory Filings** and related correspondence submitted to Regulatory Authorities or received from Regulatory Authorities with respect to such Program.

Celgene shall provide the JRC with a summary of material clinical protocols and **Regulatory Filings** with respect to each Celgene Development Compound.

Upon the request of Globelimmune, Celgene shall provide Globelimmune with copies of material **Regulatory Filings** and related material correspondence submitted to Regulatory Authorities or received from Regulatory Authorities with respect to any such Celgene Development Compound.

Licensee shall be responsible for all correspondence, meetings and other interactions, with the relevant Regulatory Authorities concerning regulatory activities related to the Product in the Field in the Licensee Territory, and for preparing and filing any and all **Regulatory Filings** for Regulatory Approval for the Product in the Field in the Licensee Territory at its sole expense and shall use Commercially Reasonable Efforts in doing so.

## More definitions of Regulatory Filings

**Regulatory Filings** means, collectively: (a) all INDs, NDAs, BLAs, CTAs, establishment license applications, drug master <sup>CLOSE</sup>file applications for designation as an "Orphan Product" under the Orphan Drug Act, and all other similar submissions (including MAAs and counterparts to any of the foregoing in any country or region in the Territory) as may be required by any Regulatory Authority for the development, manufacture, use or commercialization of a Collaboration Product in the Territory; (b) all supplements and amendments to any of the

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**BASED ON 32 DOCUMENTS**

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**Regulatory Filings** means all applications, filings, dossiers and the like submitted to a Regulatory Authority for the purpose of obtaining Regulatory Approval from that Regulatory Authority. Regulatory Filings shall include, but not be limited to, all INDs, NDAs and other Regulatory Approval applications and their equivalents in the Territory.

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**BASED ON 17 DOCUMENTS**

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**Regulatory Filings** means, with respect to the Product in the Field in the Territory, all applications, registrations, submissions, dossiers, notifications, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from the Regulatory Authorities (including minutes and official contract reports relating to any communications with any Regulatory Authority) and all supporting documents and all Pre-Clinical Data, Clinical Data and CMC Data (including all Clinical Studies and Post-Approval Marketing Studies), and all data contained in any of the foregoing, including all CTNs, Drug Approval Applications, Adverse Event files and complaint files.

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**BASED ON 9 DOCUMENTS**

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