

Dear Mike Profetto,

your application package for Pragmatic Data's electronic submission services has been emailed to you at [mprofetto@goldeagle.com](mailto:mprofetto@goldeagle.com)

The package consists of

- instructions,
- our terms and conditions,
- a customized authorization letter

Please read the instructions and the terms and conditions carefully.

Print the authorization letter page onto your official company letterhead.

Sign with your traditional handwritten signature as the contact person.

The company's VP - Product Engineering, Mike Profetto, who you named on the application as one with the authority to sign legally binding documents for Gold Eagle Co., must sign the printed authorization letter.

Scan the signed authorization letter and return it as an image or PDF attachment to [esg@pragmaticdata.com](mailto:esg@pragmaticdata.com) (e.g., by replying to this email).

In addition, send the letter by paper mail to the address shown on the letter.

**NOTE:** Even though you may have access soon after return of the scanned copy by email, if your letter is not also received by paper mail, your access to the service will be suspended. Likewise, if the electronic letter you submitted is not completely signed, or if the signing person is not an authorized representation of Gold Eagle Co., or if you made any other misrepresentation, Pragmatic Data will consider this fraud and reserves the right to ban you or Gold Eagle Co. from accessing our services, and to initiate legal actions against you.

## Instructions for Pragmatic Regulatory Submission Services

The package consists of

- instructions,
- our terms and conditions,
- a customized authorization letter

Please read the instructions and the terms and conditions carefully.

Print the authorization letter page onto your official company letterhead.

Sign with your traditional handwritten signature as the contact person.

An officer of the company who you named on the application as one with the authority to sign legally binding documents, must sign the printed authorization letter.

Scan the signed authorization letter and return it as an image or PDF attachment to [esg@pragmaticdata.com](mailto:esg@pragmaticdata.com) (e.g., by replying to the email that delivered this application package).

In addition, send the letter by paper mail to the address shown on the letter:

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# Terms and Conditions for Using the Pragmatic Regulatory Submission Services

Effective Date: May 14, 2014.

Pragmatic Data LLC (WE) is providing regulatory submission authoring, validation, and submission services under the terms and conditions detailed below. By using this service YOU, the user, are agreeing with these terms of use. YOU may be asked to explicitly sign this agreement at an opportune time when WE collect information from YOU. YOUR signature then affirms YOUR agreement. However, YOUR agreement to the current terms and conditions is renewed every time YOU use our services. YOU understand that the terms and conditions may change at any time even without special notice and request for YOU to sign the agreement again.

## The Services

WE may provide regulatory submissions services of three kinds (1) Tools, e.g., Authoring Tools and Validation Tools, (2) Transmission Services, and (3) trouble shooting assistance.

By “Regulatory Submissions”, or “Submissions” we mean any data, document, message, form, or any other unit or assembly of data which YOU create for the intent of eventually submitting said data to a regulatory agency. Even though “Submission” implies the verb “to submit” no actual act of submitting such data to the agency takes place unless YOU specifically send the submissions to the agency or cause us to perform such a transmission on YOUR behalf using our Transmission Services.

(1) Tools are provided in the form of end-user applications via the Internet which YOU use through YOUR computer, network resources, and necessary programs such as web browser, etc. YOU are responsible of owning the appropriate resources. WE make efforts to support standard web browsers commonly available on the market in reasonably current versions. However WE do not warrant that all web browsers in all versions and all computer and operating system configurations are supported. Any configurations WE may suggest to YOU to use our tools are performed by YOU at YOUR own discretion and risk.

The Tools WE provide do not retain YOUR work or data which YOU enter; as necessary they may provide the functions for YOU to save YOUR work or data to YOUR computer and it is YOUR responsibility to use these functions and any functions that YOUR web browser, operating system, and computer provide to save YOUR data, this includes saving of web pages, selecting and copying of data and pasting into files or documents on YOUR computer, screen shots, etc. WE are never responsible for saving YOUR data.

Authoring Tools are provided in the hope that they are useful to YOU to create regulatory submissions.. The correct functioning of these authoring tools has been validated over time as users have authored regulatory submissions and said submissions have passed validation by the regulatory agency, and Pragmatic Data LLC has not been made aware of substantial problems with the submissions so authored. To the extent that Pragmatic Data LLC has been informed of malfunctions or errors introduced into submissions by our tools, we make efforts to resolve such malfunctions. Malfunctions may be detected by failure of submissions to validate or agency rejections, but may also be missed. It is YOUR responsibility to review all submission and verify that the submissions have the intended effects upon processed between YOU and the agency.

Validation Tools are provided to detect many errors but can not detect all possible errors. Passing validation services without errors does not mean YOUR submission will be accepted by the agency. And in no case does submission to validation tools mean an actual transmission to the agency.

(2) Transmission Services are provided when YOU agree to submit YOUR data to the regulatory agency. This will be an explicit interaction so that YOU will be advised of its occurrence. WE will then make a best effort to transmit YOUR submission to the agency and YOU will be advised whether YOUR submission has been successfully transmitted to the agency. Successful transmission may not mean the agency has accepted YOUR submission, and WE are not responsible for YOUR submission being actually accepted by the agency. WE will make efforts to transmit back to YOU any rejections and errors that are sent to us from the agency. Such transmission will use the email address which YOU provided. If there is any malfunction.

of the email address YOU provided at the time of the submission, then YOU may not be informed of such rejections we may receive from the agency. It is YOUR responsibility to monitor YOUR email and the processing inside the agency, for example, by monitoring the appearance of YOUR data the agency's public data releases. As an example, for SPL product listing submissions, it is YOUR responsibility to monitor the appearance of YOUR listing or update thereof on DailyMed or Labels@FDA. YOU may also need to contact the agency directly to require on the status of YOUR submissions.

(3) **Trouble Shooting Services** may be provided when YOU contact us. Unless a specific service level agreement has been executed between YOU and Pragmatic Data LLC, WE may reply to YOUR request on a best effort basis and may reply late or YOU may not receive any reply from us. Any delays that this may cause regarding YOUR requirements toward any regulatory agencies are YOUR responsibility. Communication to Pragmatic Data LLC is not communication to the agency.

## **NO WARRANTY**

**DISCLAIMER.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, PRAGMATIC DATA AND ITS LICENSORS AND SUPPLIERS DISCLAIM ALL WARRANTIES, CONDITIONS, REPRESENTATIONS, INDEMNITIES AND GUARANTEES WITH RESPECT TO THIS SERVICE, WHETHER EXPRESS OR IMPLIED, ARISING BY LAW, CUSTOM, PRIOR ORAL OR WRITTEN STATEMENTS OR OTHERWISE (INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT). BY WAY OF EXAMPLE AND NOT IN LIMITATION, NEITHER PRAGMATIC DATA NOR ITS LICENSORS OR SUPPLIERS WARRANTS THAT: (i) USE OF THE SERVICE OR ANY PART THEREOF WILL BE UNINTERRUPTED OR ERROR FREE; (ii) ALL DEFECTS IN THE SERVICE WILL BE CORRECTED; OR (iii) THE SERVICE WILL OPERATE IN THE COMBINATIONS THAT MAY BE SELECTED BY YOU. TO THE EXTENT THAT PRAGMATIC DATA OR ITS LICENSORS OR SUPPLIERS CANNOT DISCLAIM A WARRANTY AS A MATTER OF APPLICABLE LAW, THE SCOPE AND DURATION OF SUCH WARRANTY WILL BE THE MINIMUM PERMITTED UNDER SUCH LAW.

**LIMITATION OF LIABILITY.** IN NO EVENT WILL PRAGMATIC DATA OR ITS LICENSORS OR SUPPLIERS BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY CHARACTER ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SERVICE, REGARDLESS OF THE LEGAL THEORY ASSERTED, WHETHER BASED ON BREACH OF CONTRACT, BREACH OF WARRANTY, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY, OR OTHERWISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND EVEN IF A REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. THE AGGREGATE AND TOTAL LIABILITY OF PRAGMATIC DATA AND ITS LICENSORS AND SUPPLIERS FOR ANY AND ALL CLAIMS ARISING OUT OF THIS AGREEMENT WILL BE LIMITED TO DIRECT DAMAGES AND WILL NOT EXCEED THE AMOUNT ACTUALLY PAID BY YOU FOR THE SERVICE THAT CAUSED THE DAMAGES

**LIMITATION OF LIABILITY FOR VALIDATOR.** While the Pragmatic Validator Service provides validation functions for conformance of SPL labels with published conformance rules, it is virtually impossible to guaranty that each and every non-conformance situation can be forseen or detected. THEREFORE, PRAGMATIC DATA EXPRESSLY DISCLAIMS ALL WARRANTY THAT THE PRAGMATIC VALIDATOR SERVICE PRODUCT WILL DETECT ANY PARTICULAR CONFORMANCE VIOLATION OR PROVIDE ANY PARTICULAR AMOUNT OF WARNING OF A POSSIBLE NON-CONFORMANCE OF A EXAMINED SPL LABEL.

**Modification and Termination of Service:** Pragmatic Data may modify the Agreement or terminate the Service at any time and publish the terms of service.

**Effective Date:** Since multiple copies of terms of services may exist, sent to YOU explicitly or be accessible on resources on our web sites, an effective date is provided to indicate how current the terms of service are. The terms of service with the latest effective date take precedence over the terms of service with an earlier or no effective date.

## Ownership and Confidentiality

**Proprietary Rights.** All trademarks, service marks, patents, copyrights, trade secrets and other intellectual property rights in the Software (collectively, "Materials") are and will remain the exclusive property of Pragmatic Data or its licensors or suppliers, whether or not specifically recognized or perfected under applicable local law. YOU will not create derivative works of, modify, assign, sublicense, sell, rent, reverse engineer, disassemble or decompile the Materials. Any rights not expressly granted herein are reserved to Pragmatic Data or its licensors or suppliers. Pragmatic Data or its licensors or suppliers will own all rights in all derivative works of the Materials and any copy, translation, modification, adaptation or derivation (including any improvement or development) of the Materials. YOU will not take any action that jeopardizes Pragmatic Data's or its licensors' or suppliers' proprietary rights in the Materials or acquire any right in the Materials.

**Confidential Information.** Confidential Information means all information that is proprietary to YOU or to Pragmatic Data or its licensors or suppliers. Confidential Information does not include: (i) information that is made generally available to the public without obligation of confidentiality; (ii) information that the receiving party can show through documentation was independently developed by the receiving party without use of Confidential Information of the disclosing party; or (iii) information that is disclosed pursuant to a requirement of a court, government agency, or law, including without limitation, state and federal securities laws; provided that, if the receiving party is required by a court, government agency, or applicable law to disclose any Confidential Information of the disclosing party, the receiving party will notify the disclosing party immediately upon learning of such requirement so that the disclosing party has an opportunity to take action to protect the confidentiality and proprietary nature of the Confidential Information. The Software is Confidential Information of Pragmatic Data.

**Nondisclosure.** Each party receiving Confidential Information of the other party will take reasonable precautions necessary to safeguard the confidentiality of the disclosing party's Confidential Information, including at a minimum, the precautions taken by the receiving party to protect its own Confidential Information. Neither party will disclose the other party's Confidential Information in whole or in part to any third party except to employees or consultants who require access to the Confidential Information, provided that any such employees and consultants agree in writing to maintain the information in confidence. Neither party will remove or deface, or allow the removal or defacement, of any confidential or proprietary notice placed on any Confidential Information of the other party.

**Security of Submissions on Pragmatic Data Computers:** WE do not store YOUR submissions on our servers except temporarily for the delivery of our services. Unless expressly mentioned otherwise, WE assume that YOUR submissions do not contain confidential patient information and only contain confidential business data to the extent that it should not be routinely published. WE make no representation that Pragmatic Data or its contractors, such as hosting service providers, comply to any specific security level for data that is temporarily stored on our computers.

**Security of Submissions on the Internet:** YOU are responsible to ensure that the security of the connection and transmissions between YOUR computer and our Tools and Services are sufficiently secure for YOUR purposes. YOU are aware of the level of security of data on the Internet, including, but not limited to, the use of HTTP, HTTPS, and email protocols. It is YOUR responsibility to assure that YOUR use of our services meets YOUR security standards.

**Security of Submissions Transmitted to the Agency:** transmissions from our systems to the agency use the HTTPS (Secure Hypertext Transport Protocol). YOU understand the level of security provided by this protocol and YOU agree not to use our Transmission Services if this level of security is not sufficient for YOUR requirements.

## Appropriate Use of Transmission Services

YOU agree to use the Transmission Services only for regulatory submissions which YOU are authorized to perform, that YOU submit only data that are true to the best of YOUR knowledge. YOU understand that any misuse of the Transmission constitutes a violation of the terms of use and possibly the crimes of perjury and fraud.

**Notification Email:** YOU have informed Pragmatic Data in a letter of authorization and non-repudiation of a contact email address. All transmissions sent to the agency putatively on YOUR behalf will be copied by email to that contact email address. YOU consent that your electronic submissions be sent to this email address.

**Security Consent:** YOU understand that it is technically not impossible for non-authorized users to enter and cause to transmit submissions impersonating the authorized user by using his contact email address and electronic signature, and YOU agree to monitor said contact email address for any notifications of submissions which YOU may not have authorized, and that you will verify the notifications carefully to ensure that such submissions have been duly authorized by YOU.

**Indemnification.** YOU agree to indemnify and hold Pragmatic Data harmless for any consequences of erroneous or false submissions made using your contact email and electronic signature.

## **General**

**Governing Law.** This Agreement will be governed by and construed in accordance with the laws of Indiana, U.S.A., as applied to agreements entered into and to be performed entirely within the state of Indiana without regard to conflicts of laws provisions thereof, the Uniform Commercial Code as adopted in Indiana or the United Nations Convention on Contracts for the Sale of Goods.

**Jurisdiction and Legal Actions.** This Agreement and Pragmatic Data services are governed by the laws of the State of Indiana. YOU hereby consent to the jurisdiction of the State of Indiana and the court venue of Indianapolis / Marion County, Indiana. Any legal or equitable claim of any nature arising hereunder will be filed and maintained in the state or federal courts in the State of Indiana and YOU agree that such courts are a convenient forum for adjudication. The prevailing party in any legal action arising hereunder will be entitled to its costs of litigation and reasonable attorneys' fees as to that part of the litigation for which it prevails.

**English Language; Headings.** Pragmatic Data and YOU confirm that it is their wish that this Agreement as well as other documents relating hereto, including notices, have been and will be drawn up in the English language only. The headings of this Agreement are inserted only for convenience and will not be construed as a part of this Agreement.

**Severability.** If any term of this Agreement is to any extent illegal, otherwise invalid, or incapable of being enforced, such term shall be excluded to the extent of such invalidity or unenforceability; all other terms hereof shall remain in full force and effect; and, to the extent permitted and possible, the invalid or unenforceable term shall be deemed replaced by a term that is valid and enforceable and that comes closest to expressing the intention of such invalid or unenforceable term.

**Entire Agreement.** This Agreement including its exhibits is the complete and exclusive statement of agreement concerning the subject matter hereof and supersedes all prior understandings and other communications between the parties relating hereto. This Agreement may be amended only by a subsequent writing that specifically refers to this Agreement and that it is signed by both parties.

To: Pragmatic Data LLC  
Electronic Submission Services  
P.O. Box 90231  
Indianapolis, IN 46290-0231

Date: March 30, 2020

Re: Transmission Authorization, Agreement, and Electronic Signature Certification Statement



To Whom It May Concern:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that we, the company named Gold Eagle Co. ("The Company") and represented with due authority by the undersigned and using this letterhead, seal and signatures, are authorized to make, and authorize Pragmatic Data LLC to transmit, electronic regulatory submissions to the U.S. FDA in our name for submissions including:

(1) product listings with the following NDC labeler codes or as such NDC labeler codes shall in the future be successfully registered with the FDA via Pragmatic Data,

(2) registrations of NDC labelers, establishment, facilities, etc. using the following owner/registrant organization DUNS numbers 230017994

and all other types of regulatory submissions which we use Pragmatic Data's services to perform.

We declare that the person named Mike Profetto ("The Contact Person"), who responds to the email mprofetto@goldeagle.com and phone +1-773-491-1944 is an authorized representative, agent, or employee of The Company and that The Company intends the electronic signature "Mike Profetto" executed by said Contact Person, located anywhere in the world, are the legally binding equivalent of this traditional hand-written signature **Mike Profetto** on behalf of the company for said regulatory submission purposes.

Digitally signed by Mike Profetto  
DN: cn=Mike Profetto, o=Gold Eagle Co., ou=Product Engineering, email=mprofetto@goldeagle.com, c=US  
Date: 2020.03.30 09:52:55 -0500

The Company affirms to have read and understood and agrees to comply and be bound by the terms and conditions that have been delivered along with the text of this authorization letter.

Sincerely yours,

**Mike Profetto**

Digitally signed by Mike Profetto  
DN: cn=Mike Profetto, o=Gold Eagle Co., ou=Product Engineering, email=mprofetto@goldeagle.com, c=US  
Date: 2020.03.30 09:52:53 -0500

Signature of Company Representative

Print: Mike Profetto

Title: VP - Product Engineering