

Instructions for completing the CTP Portal IAM Request Cover Letter and Rules of Behavior (ROB)

Please read these instructions carefully before completing.

To obtain a CTP Portal account for regulatory submissions, each Tobacco product manufacturer will need to designate an Industry Account Manager (IAM). The process for designating an IAM requires that you first complete the following:

- The IAM Request Cover Letter
- A Rules of Behavior (ROB)

The IAM Cover Letter provides CTP with the information needed to establish the CTP Portal Account and is available below. Samples of the IAM Cover Letters are provided for your information on the [IAM Request Webpage](#).

The Rules of Behavior (ROB) agreement lists specific rules for use of the CTP Portal is below. Samples of the IAM ROBs are provided for your information on the [IAM Request Webpage](#).

The following are definitions for clarification on the purpose of the requested information to complete the IAM Cover Letter and ROB. You can also find definitions for general CTP terms in the [CTP Glossary](#). To ensure your submission is processed in a timely fashion, please make sure you accurately provide all the requested information.

If you have any questions about completing your CTP Portal application, you can visit the “[Submit Documents via The CTP Portal](#)” site.

Applicant is the Tobacco product manufacturer seeking the CTP Portal account, not an individual requesting IAM status. The account will be created specifically for access to all documented tobacco product regulatory submissions registered under this manufacturer name. For these reasons, it is important that you provide the precise name of the company as it is legally registered as a place of business. For future submissions, consistently use the same name to ensure that all submissions are correctly associated with your manufacturer name. Any change in the Applicant name could result in subsequent submissions not being associated and thereby not available for viewing when you access the CTP Portal account.

Addresses refers to the three required addresses; Applicant, IAM, and Point of Contact. Each should be clearly stated. For an international applicant/manufacturer, it is very important to provide your country or province codes to ensure CTP has your correct address.

Agent is a third-party representative that has been given permission by the Applicant (manufacturer) to act on their behalf and assume the IAM role. FDA requires a signed IAM Request Cover letter and ROB for each Applicant that an Agent represents. For example, attorneys have often been designated as Agents for tobacco manufacturers.

IAM is the person designated by the applicant to create and manage all CTP Portal user accounts for the Applicant. We recommend that the IAM be a direct employee of the Applicant. However, a third-party representative known as an Agent, may also be the IAM. **Note:** If an Agent or the designated IAM no longer represents your organization, it will be your responsibility as the Applicant to make sure the IAM role is properly transferred and the previous IAM deactivated.

¹Applicant may include tobacco manufacturers, importers, or sponsors that submit regulatory documents to FDA, not representatives thereof.

IAM Employer is the employer of the designated IAM. The IAM employer could be the Applicant (if they are a direct employee of the Applicant) or the Agent (a third-party representative). For an Agent, the IAM employer cannot be the Applicant.

Certification Statement should have the Applicant name clearly stated in the empty bracketed space.

Point of Contact (POC) is an employee or Agent of the Applicant who is authorized to send and receive communications from CTP on behalf of the Applicant. The IAM can also be the POC, though the POC role is different from the IAM role. The IAM role is limited to official regulatory submissions, communications and management using the CTP Portal account. Whereas POC will receive all correspondence from CTP either electronically or by mail, communicate directly with the CTP assigned Project Manager, not regulatory submissions to the CTP Portal. The POC is especially important for companies new to CTP to establish a first line of contact when information needs to be communicated to the Applicant.

Cover Letter Signature must be that of the authorizing representative (a person who is a corporate or executive officer with signatory powers, a general partner, proprietor or a duly authorized representative that has the authority to sign contracts, permits, applications and other documents in the company's name) from the Applicant manufacturer. It cannot be the signature of the Agent; the signature of the Applicant is required to show permission has been given to the Agent to represent them.

Rules of Behavior (ROB) must state the Applicant's name, date and signature of the IAM. If the IAM is an Agent, the Agent's name and signature must also be provided on the ROB. By signing the ROB, you are certifying that you, as the IAM, accept the ROB.

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CTP Portal IAM Request Cover Letter and Rules of Behavior (ROB)

Date: _____

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: CTP Portal IAM Account for _____
(Manufacturer/Applicant Name)

To CTP Document Control Center:

We are requesting the creation of a CTP Portal user account designating the following person as the Industry Account Manager (IAM):

Applicant Name *(must be exact business name of the company):*

Applicant Address *(Street address, City, Zip Code, Country or Province Code):*

IAM Name *(Last, First and Middle Initial):* _____

IAM Employer *(Can be different from the Applicant, if an Agent):*

IAM Address *(Street address, City, Zip Code, Country or Province Code):*

IAM Email address: _____

IAM Phone number: _____

Certification statement to comply with 21 CFR 11.100 such as: Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [_____, _____], intends that all electronic signatures executed by its employees, agents, or representatives thereof, located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures.

POC Name *(Last, First and Middle Initial. POC can be [but is not required to be] different from the IAM):*

POC Applicant Address: _____
(Street address, City, Zip Code, Country or Province Code. POC can be [but is not required to be] different from Applicant address)

POC Applicant Email *(Can be [but is not required to be] different from the IAM):*

POC Applicant Phone number *(Can be [but is not required to be] different from the IAM):*

Sincerely,

(must be signed by authorizing Applicant employee)

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Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

CTP Portal Industry Account Manager

Rules of Behavior

As the Industry Account Manager (IAM) for the applicant listed below, you agree to these Rules of Behavior:

- You must conduct only authorized business on the system.
- You must maintain the confidentiality of your account information such as your password.
- You must follow proper logon/log out procedures. Do not store your password locally on your system or utilize any automated logon capabilities. You must promptly log out when session access is no longer needed. If a log out function is unavailable, you must close your browser. Never leave your computer unattended while logged into the system.
- You must report all security incidents or suspected incidents (e.g., lost passwords, improper or suspicious acts) to the FDA Systems Management Center at SMC_Cyberops@fda.hhs.gov. You must immediately change your password if it is compromised or suspected to have been compromised.
- You must not establish any unauthorized connections between systems, networks, and applications owned by the FDA.
- Your access to systems and networks owned by the FDA is governed by, and subject to, all Federal laws, including, but not limited to, the Privacy Act, 5 U.S.C. 552a.
- You must not browse, search or reveal information hosted by the FDA except in accordance with that which is required to perform your legitimate tasks or assigned duties.
- You agree to contact the CTP eSubmissions Helpdesk at CTPeSub@fda.hhs.gov if you do not understand any of these rules.
- As an IAM, you agree to create and manage the CTP Portal Accounts on behalf of the Manufacturer that you represent, this includes the deactivation of accounts (*e.g. when employees leave or agents change*), changing an account holder's access level, resetting a user's account that have become deactivated, and unlocking user accounts that become locked.
- As an IAM, you understand that accounts will only exist in CTP Portal for the tobacco manufacturers as defined under section 900(20) of the Family Smoking Prevention and Tobacco Act (PL 111-31), not for the companies that may represent them. An IAM will administer the user accounts under separate tobacco manufacturer accounts, for each tobacco manufacturer they represent. For example, if you are an agent and serve the role of IAM for multiple tobacco product manufacturers, you will have and be responsible for managing a separate user account for each tobacco product manufacturer you represent.
- You will regularly review the list of accounts established for the applicant to determine whether each user's access is appropriate.

IAM Signature:	Date:
IAM Printed Name:	
Applicant (i.e. Company) Name:	

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