

Covers drug, biologic, and medical device manufacturers, distributors, and developers, including contract manufacturers and research companies. Supplements and cosmetics use CWCO-SUP-SUPP. Complete with ACORD 125 and 126. Attach product list and five-year loss runs.

1 APPLICANT / BUSINESS INFORMATION

LEGAL BUSINESS NAME

DBA

FEIN

YEARS IN BUSINESS

BUSINESS ADDRESS

CITY / STATE / ZIP

WEBSITE

Entity type:

☐ Sole proprietor

☐ Partnership

☐ LLC

☐ Corporation

PRIMARY CONTACT / TITLE

PHONE

EMAIL

FDA ESTABLISHMENT REGISTRATION / FEI NO.

FOR PROFIT / NOT FOR PROFIT

2 OPERATIONS

Products (check all that apply):

☐ Prescription drugs

☐ OTC drugs

☐ Biologics

☐ Class I devices

☐ Class II devices

☐ Class III devices

☐ Diagnostics / IVD

☐ Contract manufacturing for others

| PRODUCT / SERVICE | ROLE (M / D / R / I) | % OF REVENUE | SOLD TO |
|-------------------|----------------------|--------------|---------|
|                   |                      |              |         |
|                   |                      |              |         |
|                   |                      |              |         |
|                   |                      |              |         |
|                   |                      |              |         |
|                   |                      |              |         |

Role: M = manufacturer; D = distributor; R = relabeler / repackager; I = importer. Sold to: hospitals, physicians, pharmacies, consumers, other manufacturers.

2-1 Does the business manufacture or assemble finished medical devices?

☐ Yes

☐ No

IF YES, EXPLAIN

2-2 Are any products used in clinical trials or other human testing?

☐ Yes

☐ No

IF YES, EXPLAIN

2-3 Does the business make or distribute controlled substances?

☐ Yes

☐ No

IF YES, EXPLAIN

2-4 Are any products implanted, life-sustaining, or sold sterile?

☐ Yes

☐ No

IF YES, EXPLAIN

3 EXPOSURE & RISK QUESTIONS — QUALITY SYSTEMS, ADVERSE EVENTS, RECALLS & TRIALS

FDA's device quality rule was rewritten around ISO 13485 and took effect in February 2026. Product claims in this class most often follow adverse events, recalls, clinical trial injuries, and promotion outside the approved label.

3-1 If yes to 2-1, has the quality system been updated to meet FDA's QMSR (ISO 13485-based) effective February 2026?

☐ Yes

☐ No

IF YES, EXPLAIN

3-2 If yes to 2-1, is the business ISO 13485 certified?

☐ Yes

☐ No

IF NO, EXPLAIN

3-3 For drugs and biologics, are operations compliant with cGMP (21 CFR Parts 210/211)?

☐ Yes

☐ No

IF YES, EXPLAIN

|                 |                                                                                                                        |                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| 3-4             | Are adverse events reported to FDA (MedWatch / MDR) within required timeframes?                                        | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF NO, EXPLAIN  |                                                                                                                        |                                                          |
| 3-5             | Is there a written recall program?                                                                                     | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                                        |                                                          |
| 3-6             | If yes to 2-2, is every trial covered by dedicated clinical trials insurance meeting sponsor and country requirements? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                                        |                                                          |
| 3-7             | If yes to 2-2, is informed consent documented for every trial participant?                                             | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF NO, EXPLAIN  |                                                                                                                        |                                                          |
| 3-8             | If yes to 2-2, is IRB (ethics committee) approval obtained for every trial?                                            | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF NO, EXPLAIN  |                                                                                                                        |                                                          |
| 3-9             | Does the business promote any product for uses outside its approved labeling?                                          | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                                        |                                                          |
| 3-10            | Do any products carry a Black Box warning?                                                                             | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                                        |                                                          |
| 3-11            | Has the business had a recall, FDA Form 483, warning letter, or product claim in the last 5 years?                     | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                                        |                                                          |

#### 4 EXPOSURE & RISK QUESTIONS — MANUFACTURING, SUPPLIERS & HAZARDS

|                 |                                                                                                             |                                                          |
|-----------------|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| 4-1             | Are critical suppliers qualified and audited under written quality agreements?                              | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF NO, EXPLAIN  |                                                                                                             |                                                          |
| 4-2             | Do suppliers and contract manufacturers carry products liability naming the business as additional insured? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-3             | Can every lot or serial number be traced to its components and customers?                                   | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-4             | Are labels, instructions, and promotional materials reviewed by regulatory counsel?                         | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF NO, EXPLAIN  |                                                                                                             |                                                          |
| 4-5             | Does the business import products or raw materials directly?                                                | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-6             | If yes to 2-3, is DEA registration current?                                                                 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-7             | If yes to 2-3, are DEA security and record-keeping requirements met?                                        | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-8             | Are hazardous materials kept on the premises?                                                               | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-9             | Are laboratory animals kept on the premises?                                                                | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-10            | Does the business train customers on product use?                                                           | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |
| 4-11            | Does the business provide maintenance or repair services?                                                   | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| IF YES, EXPLAIN |                                                                                                             |                                                          |

**5 REVENUE**

|                            |                               |                      |
|----------------------------|-------------------------------|----------------------|
| ANNUAL REVENUE — U.S. (\$) | ANNUAL REVENUE — FOREIGN (\$) | R&D SPEND (\$)       |
| <input type="text"/>       | <input type="text"/>          | <input type="text"/> |

**6 PRIOR INSURANCE & LOSS HISTORY**

Attach currently valued loss runs for the last 5 years.

|                                     |                                  |                      |
|-------------------------------------|----------------------------------|----------------------|
| PRODUCTS LIABILITY CARRIER / LIMITS | CLINICAL TRIALS COVERAGE (Y / N) | RETROACTIVE DATE     |
| <input type="text"/>                | <input type="text"/>             | <input type="text"/> |

6-1 Has any carrier declined, cancelled, or non-renewed coverage in the last 5 years? ☐ Yes ☐ No

IF YES, EXPLAIN

| DATE OF LOSS         | DESCRIPTION          | TOTAL INCURRED (\$)  | OPEN / CLOSED        |
|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

6-2 Is the applicant aware of any incident, complaint, or circumstance not yet resulting in a claim that could reasonably give rise to one? ☐ Yes ☐ No

IF YES, EXPLAIN

**7 RISK MANAGEMENT**

7-1 Are customer complaints investigated and trended under written procedures? ☐ Yes ☐ No

IF YES, EXPLAIN

7-2 Are new products planned for launch in the next 12 months? ☐ Yes ☐ No

IF YES, EXPLAIN

**8 SIGNATURE & FRAUD WARNING**

The undersigned declares that the statements and answers given in this supplemental are true, complete and correct to the best of their knowledge, and that no material fact has been withheld or misstated. The applicant agrees that this supplemental, together with all ACORD applications and attachments, forms the basis of any submission to insurers and may be relied upon by them. Signing this supplemental does not bind coverage. This supplemental is an intake document prepared by Cory Washington & Co. LLC to support carrier submission; it does not itself provide coverage.

**FRAUD NOTICE:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, may be committing a fraudulent insurance act, which is a crime and may subject such person to criminal and civil penalties. State-specific fraud warnings appear on the insurer's application.

|                                                   |                                     |                      |
|---------------------------------------------------|-------------------------------------|----------------------|
| APPLICANT / AUTHORIZED SIGNATURE (TYPE FULL NAME) | TITLE                               | DATE                 |
| <input type="text"/>                              | <input type="text"/>                | <input type="text"/> |
| PRODUCER — CORY WASHINGTON & CO. LLC              | PRODUCER SIGNATURE (TYPE FULL NAME) | DATE                 |
| <input type="text"/>                              | <input type="text"/>                | <input type="text"/> |