Covers pharmaceuticals, biologics, dietary supplements marketed with drug-like claims, and medical devices. Complete with CWCO-SUP-CORE and ACORD 125/126. Attach a product brochure or catalog, cu

NAMED INSURED	ADDITIONAL NAMED INSUREDS	EFFECTIVE DATE	WEBSITE

MAILING ADDRESS	PREMISES ADDRESS (IF DIFFERENT)	CITY / STATE / ZIP

AUDIT / INSPECTION CONTACT	CONTACT PHONE	CONTACT EMAIL

Applicant is a:

☐ Corporation ☐ Individual ☐ Partnership
☐ LLC ☐ Joint venture ☐ Other

Enterprise is:

☐ For profit ☐ Not for profit ☐ Other

This submission is primarily:

☐ A drug / biologic / supplement (complete Sec
☐ A medical device (complete Section E)
☐ Both (complete Sections D and E)

A OPERATIONS & SALES

WHAT ARE THE APPLICANT'S OPERATIONS?

PERIOD	GROSS REVENUES — DOMESTIC ($)	GROSS REVENUES — FOREIGN ($)	TOTAL ($)

Complete rows for: upcoming year (est.), last 12 months, one year prior, two years prior, three years prior.

% OF SALES OUTSIDE THE UNITED STATES	% OF TOTAL PRODUCTS/SERVICES DOMESTIC MANUFACTURING VS. DISTRIBUTION VS. RETAIL

PRODUCTS / SERVICES	APPLICANT ACTS AS (M/W/R/I/MR/O)	% OF GROSS RECEIPTS	SOLD TO (M/W/R/C/O)	YEARS IN MARKET

Codes: M=Manufacturer, W=Wholesaler, R=Retailer, I=Importer, MR=Manufacturer's Rep., C=Consumer Direct, O=Other.

A1 Are any new products to be introduced during the next year? ☐ Yes ☐ No
IF YES, EXPLAIN

A2 Have any products been discontinued since last year? ☐ Yes ☐ No
IF YES, EXPLAIN

A3 Does the applicant directly import any products or raw materials? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to A3, attach a list of imported products/materials with percentage of total sales, manufacturer, and country of origin.

A4 Does the applicant obtain certificates of insurance including Products Liability coverage from each of its suppliers, and is it named Additional Insured? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to A4, state the minimum limits required in the explanation field.

A5 Are all warning labels, instructions, and advertising material reviewed by outside counsel? ☐ Yes ☐ No

A6 Do the applicant's products meet applicable government or industry standards? ☐ Yes ☐ No
IF YES, EXPLAIN

A7 Does the applicant comply with Good Manufacturing Practices (GMP)? ☐ Yes ☐ No
IF YES, EXPLAIN

A8 Is the applicant a member of a trade organization? ☐ Yes ☐ No
IF YES, EXPLAIN

B FORMULATION, LABELING & WHITE LABEL

B1 Does the applicant formulate its own products? ☐ Yes ☐ No
IF YES, EXPLAIN

If no to B1, identify who formulates the products in the explanation field.

B2 Are formulas reviewed, tested, and verified by an independent third party? ☐ Yes ☐ No
IF YES, EXPLAIN

B3 Does the applicant offer white-labeling services (manufacturing products sold under another entity's brand)? ☐ Yes ☐ No
IF YES, EXPLAIN

B4 Are any products sold under the applicant's own brand produced by another entity under a white-label agreement? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to B4, list the contracted manufacturers in the explanation field.

Records maintained include:

☐ When and where product was manufactured
☐ To whom product was sold and date of sale
☐ Who manufactured or supplied the product/ing
☐ Changes in formula/formulation notes
☐ Changes in advertising/packaging notes
☐ None of these

HOW LONG ARE THESE RECORDS MAINTAINED?

DOES APPLICANT HAVE A FORMAL WRITTEN QC/TESTING PROGRAM?

C REGULATORY & ADVERSE EVENT HISTORY

Applies to both drug/biologic and medical device submissions.

C1 Has the applicant been inspected by the FDA (or equivalent regulator) in the last five years? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to C1, list inspection dates in the explanation field.

C2 Was the applicant issued an FDA Form 483 or equivalent notice at any inspection? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to C2, attach the form and the applicant's written response.

C3 Has the applicant received customer complaints regarding its products in the last five years? ☐ Yes ☐ No
IF YES, EXPLAIN

C4 Have any adverse events concerning the applicant's products been reported to the applicant or the FDA in the last five years? ☐ Yes ☐ No
IF YES, EXPLAIN

C5 Has the applicant been cited by any regulatory agency for violations arising out of business activity involving its products? ☐ Yes ☐ No
IF YES, EXPLAIN

C6 Does the applicant have a formal written product recall program in place, and does it carry Product Recall insurance? ☐ Yes ☐ No
IF YES, EXPLAIN

C7 Has the applicant ever had a product recall event? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to C7, state in the explanation field: date, voluntary or ordered (and by what agency), product(s) involved, reason and discovery method, remedy, and percentage of recalled goods returned or repaired.

C8 Are there any present situations that might give rise to an incident causing a product recall? ☐ Yes ☐ No

IF YES, EXPLAIN

D DRUG, BIOLOGIC & SUPPLEMENT DETAIL

Complete this section only if the submission involves a drug, biologic, or supplement marketed with drug-like claims. Otherwise skip to Section E.

INGREDIENT / CATEGORY	% OF SALES — LAST 12 MONTHS	% OF SALES — NEXT 12 MONTHS

Categories: animal use; birth control; blood products; controlled substances; fertility treatment; hormone therapy; pediatric; SSRIs; topicals; vaccines.

DRUG TYPE	% OF PRODUCTS

Types: over-the-counter medications; generic prescriptions; brand name prescriptions. Should total 100%.

D1 Does the applicant manufacture, package, or repackage for direct-to-consumer distribution, and do labels meet FDA labeling requirements? ☐ Yes ☐ No

IF YES, EXPLAIN

D2 Do any products require a Black Box warning? ☐ Yes ☐ No

IF YES, EXPLAIN

D3 Does the applicant manufacture or distribute any Controlled Substance (per the Controlled Substances Act) or any product requiring DEA registration? ☐ Yes ☐ No

IF YES, EXPLAIN

If yes to D3, state the license number in the explanation field.

D4 Are any products currently used in a clinical trial or other test involving human subjects? ☐ Yes ☐ No

IF YES, EXPLAIN

If yes to D4, attach trial details. If professional liability coverage is sought for clinical trial conduct, a separate clinical trials supplemental is required.

D5 Does the applicant promote any product for off-label use? ☐ Yes ☐ No

IF YES, EXPLAIN

If yes to D5, attach a description of the product, its approved use, the off-label use promoted, and supporting documentation of acceptability.

E MEDICAL DEVICE DETAIL

Complete this section only if the submission involves a medical device. Otherwise skip.

DEVICE CLASS (PER FDA OR EQUIVALENT)	% OF REVENUE — LAST 12 MONTHS	% OF REVENUE — NEXT 12 MONTHS

Classes: Class I; Class II; Class III; Class IV (if applicable); Other. Should total 100%.

PRODUCT	MANUFACTURER OR DISTRIBUTOR	WHOLE PRODUCT OR COMPONENT	COUNTRY OF ORIGIN (IF DISTRIBUTED)

E1 Does the applicant manufacture and/or assemble the final device? ☐ Yes ☐ No
IF YES, EXPLAIN

E2 Are any products required to be sold sterile? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to E2, state in the explanation field whether the applicant or a third party sterilizes the product, and whether the applicant is held harmless by that third party.

E3 Does the applicant provide training on the use and maintenance of its products? ☐ Yes ☐ No

E4 Does the applicant provide maintenance or repair services for its customers? ☐ Yes ☐ No
IF YES, EXPLAIN

E5 Does the applicant subcontract maintenance or repair services to others, and is the applicant named additional insured on the subcontractor's policy? ☐ Yes ☐ No
IF YES, EXPLAIN

E6 Does the applicant conduct any contract manufacturing on behalf of third parties? ☐ Yes ☐ No
IF YES, EXPLAIN

% OF PRODUCTS MADE TO OTHERS' SPECIFICATIONS	% OF PRODUCTS MADE TO APPLICANT'S OWN SPECIFICATIONS	DOES THE THIRD PARTY PROVIDE LABELS, PACKAGING & INSTRUCTIONS?

E7 Is the applicant ISO certified (e.g., ISO 13485)? ☐ Yes ☐ No
IF YES, EXPLAIN

E8 Are laboratory animals kept on the premises? ☐ Yes ☐ No
IF YES, EXPLAIN

If yes to E8, state the type, number, and purpose of animals in the explanation field.

E9 Are any materials or products handled by the applicant hazardous, alone or in combination with other materials? ☐ Yes ☐ No
IF YES, EXPLAIN

F LOSS HISTORY & PRIOR INSURANCE

Attach currently-valued five-year loss runs, including claim detail for all losses open or exceeding $15,000.

CURRENT / EXPIRING CARRIER	LIMIT OF INSURANCE	DEDUCTIBLE ($)	PREMIUM ($)

Expiring policy is:
☐ Claims made ☐ Occurrence ☐ Offering renewal?

RETROACTIVE DATE	POLICY TERM DATES

F1 Have any Product Liability claims been made, whether or not covered by insurance? ☐ Yes ☐ No
IF YES, EXPLAIN

F2 During the past five years, has any insurer cancelled or non-renewed similar insurance, or has coverage been cancelled for nonpayment? ☐ Yes ☐ No
IF YES, EXPLAIN

F3 Is the applicant aware of any occurrence, fact, circumstance, incident, situation, damage or accident related to its operations that might reasonably give rise to a claim or lawsuit, whether valid or not? ☐ Yes ☐ No
IF YES, EXPLAIN

YEAR	# CLAIMS	TOTAL AMOUNTS PAID ($)	AMOUNTS RESERVED ($)	TOTAL INCURRED ($)	DATE OF LOSS INFO.

G ADDITIONAL INFORMATION

ANYTHING ELSE AN UNDERWRITER SHOULD KNOW — REGULATORY CERTIFICATIONS, KEY CUSTOMER CONCENTRATION, OR PLANNED CHANGES

H REPRESENTATIONS & SIGNATURE

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. The applicant acknowledges that the answers provided are based on a reasonable inquiry and/or investigation, and agrees to notify the producer of material changes arising prior to the effective date.

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, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. (State-specific fraud warnings apply; see state amendatory notice.)

APPLICANT / AUTHORIZED SIGNATURE (TYPE FULL NAME) | TITLE | DATE

PRODUCER — CORY WASHINGTON & CO. LLC | PRODUCER SIGNATURE (TYPE FULL NAME) | DATE