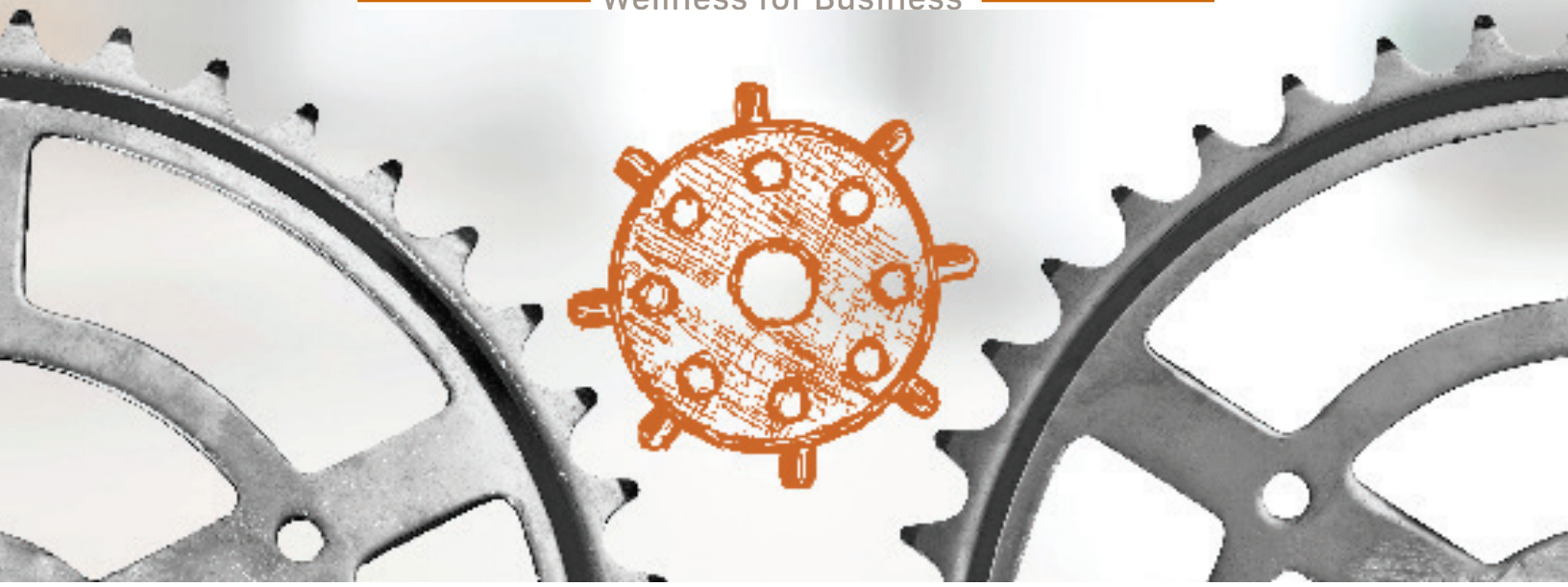
U.S. Agent Services for FDA Registered Establishments

Provided by

REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®



Regulatory Compliance Associates® Inc. (RCA) provides assistance with U.S. Registration and Service as a Registered U.S. Agent on behalf of our clients.

Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device product imported into the United States must identify a United States Agent (U.S. Agent) for that establishment.

Description of U.S. Agent Services

U.S. Agent Responsibilities

The U.S. Agent must either reside in the U.S. or maintain a place of business in the U.S. The U.S. Agent cannot use a post office box as an address. The U.S. Agent cannot use just an answering service. They must be available to answer the phone or have an employee available to answer the phone during normal business hours.

The responsibilities of the U.S. Agent are limited and include:

- Assisting FDA in communications with the foreign establishment,
- Responding to questions concerning the foreign establishment's drug or device products that are imported or offered for import into the United States,
- Assisting FDA in scheduling inspections of the foreign establishment, and
- If FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. Agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

Please note that the U.S. Agent has **no responsibility** related to reporting of adverse events under the Medical Device Reporting regulation (21 CFR Part 803), submitting 510(k) Premarket Notifications (21 CFR Part 807, Subpart E) or Postmarketing reporting of adverse drug experiences (21 CFR 314.80).

RCA 2017-2018 Fee Schedule For U.S. Agent Services

- Initial U.S. Agent Registration set-up fee: $1000.00
- Annual Establishment Registration Assistance/U.S. Agent fee: $500.00

These rates are not inclusive of the annual fee instituted by FDA for Establishment Registration in fiscal years 2017-2018.

FDA 2017-2018 Annual Registration User Fees

FDA has lowered most of its application fees, while increasing some of its other fees, such as facility fees for certain regulated products. RCA can assist your organization in determining the registration user fees based on the current published rates for the drug or device.

As U.S. Agent, RCA will invoice annually the cost of the service fee. It is the responsibility of the establishment to keep RCA informed of any changes in contact information (name, address or phone), owner operator information, or Official Correspondent. These changes are reportable within 10 days of change being effective.

All FDA related correspondence and/or documents received and/or delivered on behalf of client as a registered U.S. Agent will be billed semi-monthly at the hourly rate of $230/hour plus shipping.

Hourly rates are billed by the quarter hour and are subject to change. RCA must provide 30 days written notice of any change in rates.

5 Easy Steps To Get Started

1. **Visit the RCA Homepage at www.rcainc.com and select U.S. Agent Services under the Services tab.**
2. **Complete the simple online registration form with updated and accurate information about your company and the products you intend to list. Submit the online registration form to RCA.**
3. **An RCA U.S. Agent Services Specialist will review the information you have submitted to ensure it is complete and accurate for further processing.**
4. **RCA will send you our standard U.S. Agent Services Agreement which outlines the scope of services to be provided and details on payment. This agreement must be signed, dated, and returned to RCA for execution before services will be initiated by RCA.**
5. **Submit payment to RCA pursuant to the U.S. Agent Services Agreement.**

10411 Corporate Drive, Suite 102
Pleasant Prairie, WI 53158

www.rcainc.com