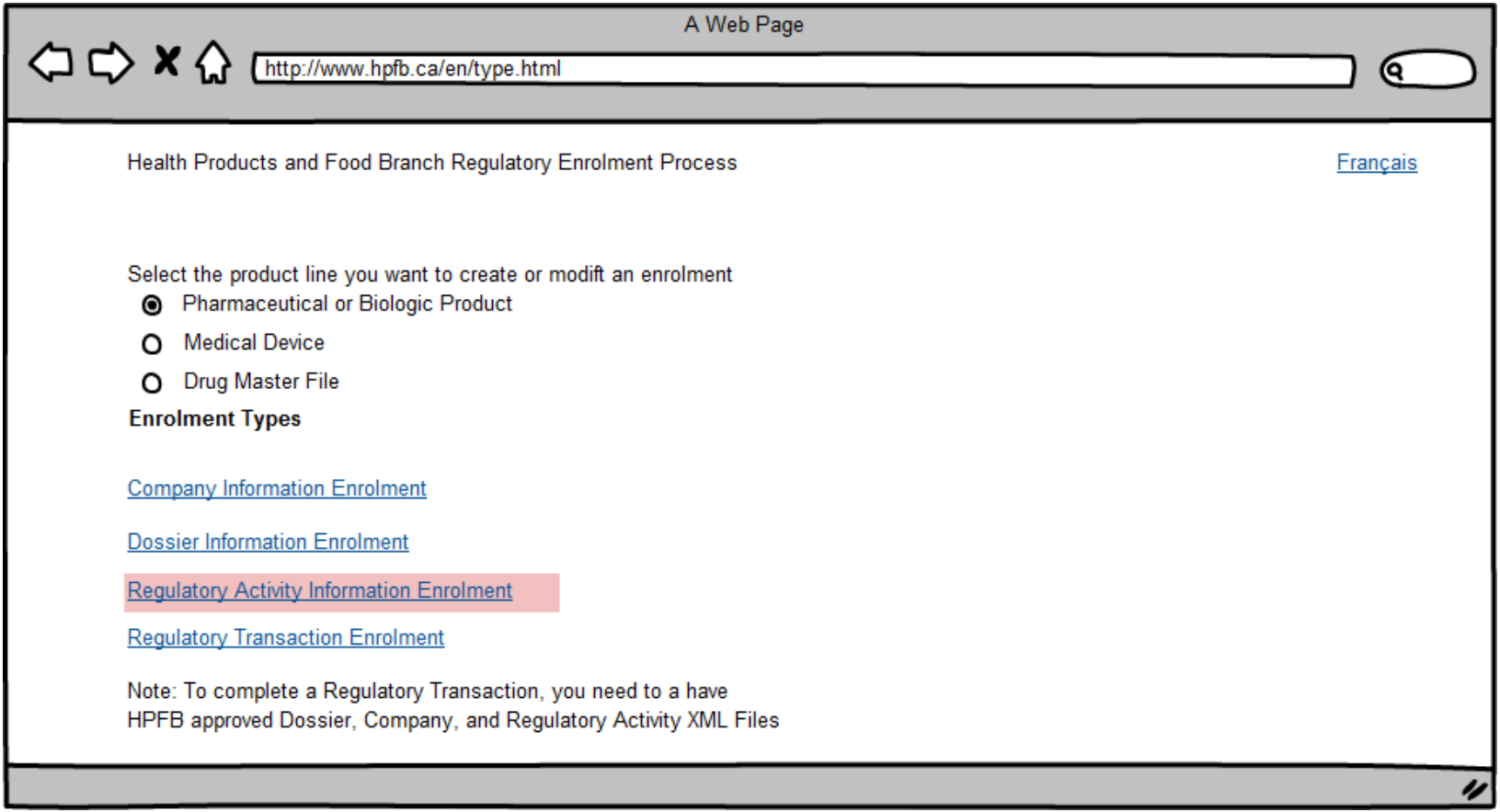
A Web Page
http://www.hpfb.ca/en/type.html
Health Products and Food Branch Regulatory Enrolment Process
Français
Select the product line you want to create or modift an enrolment
Pharmaceutical or Biologic Product
Medical Device
Drug Master File
Enrolment Types
Company Information Enrolment
Dossier Information Enrolment
Regulatory Activity Information Enrolment
Regulatory Transaction Enrolment
Note: To complete a Regulatory Transaction, you need to a have
HPFB approved Dossier, Company, and Regulatory Activity XML Files

A Web Page

http://www.hpfb.ca/en/InitateDossier.html

Home › Product Line › Regulatory Activity

Health Products and Food Branch Regulatory Enrolment Process. Intiate Pharmaceuatical Regulatory Activity

Load a Draft or Completed file

Browse

Enrolment Type

New Enrolment

Enrolment Version

1.0

Amend Enroilment

Save Draft

Proceed to step 2 of 2

A Web Page

http://www.hpfb.ca/en/regActivity.html

Home › Product Line › Regulatory Activity

Health Products and Food Branch Regulatory Enrolment Process.
Pharmaceutical Regulatory Activity

Company ID

Dossier ID

Regulatory Activity Lead

Regulatory Activity Type

Fee Class

Rationale for all SNDS, SANDS , (all human drug types); Veterinary Supplemental New Drug Submission (VSNDS), Veterinary Supplemental Abbreviated New Drug Submission (VSANDS) (all veterinary drug types); or for biological drug DIN submissions

- ☐ New Route of administration, dosage form and/or strength
- ☐ New claims/use, indications, recommended administration or dosage regime
- ☐ Change in formulation or method of manufacturing with clinical/bio data
- ☐ Change in drug substance/product (site, method, equipment, process control)
- ☐ Replace sterility test with process parametric release
- ☐ Confirmatory studies
- ☐ Other (please specify):

Type of Notifiable Change (NC) or Veterinary Notifiable Change (VNC) submission (if applicable)

- ☐ Change in text of labelling
- ☐ Change in drug substance (source, synthesis)
- ☐ Change in formulation
- ☐ Change in specifications (medicinal or non-medicinal ingredient, pharmaceutical form, analytical method)
- ☐ Change in expiry period/storage conditions
- ☐ Other (please specify):
- ☐ Change in manufacturing method
- ☐ Change in manufacturing site
- ☐ Change in container size for parenteral drug
- ☐ Change in packaging specifications for parenteral/inhalation drug
- ☐ Change in packaging material composition

☐ I confirm that this administrative submission type is NOT a LASA submission

Reason for filing this Regulatory Activity

Related Regulatory Activity

Activity Type	Date Cleared
Activity 1	22-10-2016
Activity 2	22-10-2016
Activity 3	22-10-2016

Add Related Activity | Delete Selected Related

Regulatory Activity Type: Activity 1

Date Cleared: 22-10-2016

Control Number: 123456

Dossier ID (Previously File Number)

Manufacturer or Sponsor Name

Reason for submission

Drug Identification Number (DIN)
12345678
66666666
12121212

DIN (8 digits): 12345678

Add DIN | Delete Selected DIN

Administrative Contacts for this Regulatory Activity Enrolment Process

Last Name	First Name	Telephone
Smith	Jane	416-555-4545
Guilizonni	Giacomo	613-304-1434

Contact Information

Contact Role

- ☑ Regulatory Enrolment Process Contact
- ☐ Regulatory Enrolment Process Alternate Contact

Salutation: Dr.

Given Name: Guilizzoni

Surname: Giacomo

Language of Correspondence: English

Telephone Number: 613-304-1434

Telephone Extension

Fax Number: 613-304-1434

Email

Will the submission be signed or filed by a third party on behalf of the manufacturer or sponsor? Yes

Please Submit the Authorization Letter

Back to Step 1 of 2 | Save Draft | Generate XML