NHS
Business Services Authority

Drug Tariff Part IX Annual Review 2016-2017

1. Summary

During 2016-17, 290 new applications for products to be considered for inclusion in Part IX have been received. This represents a decrease of 24% compared with 2015-16. The percentage of applications for unique products has remained similar at 9% of all applications received and 'me-too' type products have decreased to 65%; the percentage of line extensions has increased to 26% of all applications. As previously, a significant proportion of the "me-too"/ "line extensions" involved requests for listings with higher prices compared with similar products already in the Drug Tariff. Applications of this type require more information from applicants to meet the cost-effectiveness criterion with associated correspondence and data analysis.

The majority of applications received are subsequently approved. The main reasons for a delay in the process are:

- CE documents are either missing or incorrect;
- Samples missing/ incorrect;
- Insufficient information for cost-effectiveness assessment

The most common reason for applications remaining in the pending state for an extended period of time is due to the delay resulting from applicants needing time to compile additional information to support the cost effectiveness of their product.

During 2016-17, there was a 5% increase in the number of price increases requested through the price rise mechanism compared with 2015-16. The price increases for June account for 48% of the amount that were implemented in the whole period of 2016-17. Ten requests for exceptional price increases have been received this year and one was granted.

2. Introduction

The legislative basis for Part IX of the Drug Tariff is sections 126 and 164 of the National Health Service Act 2006 and regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) regulations 2013. The Drug Tariff is compiled and published on a monthly basis by NHS Prescription Services on behalf of the Secretary of State for Health, as provided for by these legislative provisions. Part IX of the Drug Tariff is the list of appliances and chemical reagents approved on behalf of the Secretary of State and which may be prescribed at NHS expense by an appropriate prescriber.

Responsibility for administration of Part IX of the Drug Tariff is shared between the Department of Health and NHS Prescription Services of the NHS Business Services Authority. The Department of Health has responsibility on all aspects of policy. NHS Prescription Services has responsibility for approval of the lists of appliances and chemical reagents on behalf of the Secretary of State for the purposes of the 2006 Act, to determine the prices on the basis of which the payment for such appliances and chemical reagents is to be calculated and to remove products from Part IX when NHS Prescription Services is notified that they are no longer available.

This paper reviews the activity of NHS Prescription Services between April 2016 and March 2017 with regards to the administration of the application process for listing in Part IX, the Part IX price increase mechanism, any applications for an exceptional price increase and the Part IX Appeal process.

3. Applications for inclusion in Part IX

The application procedure for products to be listed in Drug Tariff Part IX is set out in the Drug Tariff Guidance Notes. There are three criteria that an application must satisfy in order to be approved for listing in Part IX which are:

i. The products are safe and of good quality;
ii. They are appropriate for prescribing in primary care;
iii. They are cost effective.

Between April 2016 and March 2017, a total of 290 new applications for products to be considered for inclusion in Part IX were received. This represents a 24% decrease in the number of applications made compared to the year 2015-2016 when 381 were received. Figure 1 illustrates the total number of applications received over the previous four financial years. The average number of applications received per year over the four year period was 330.

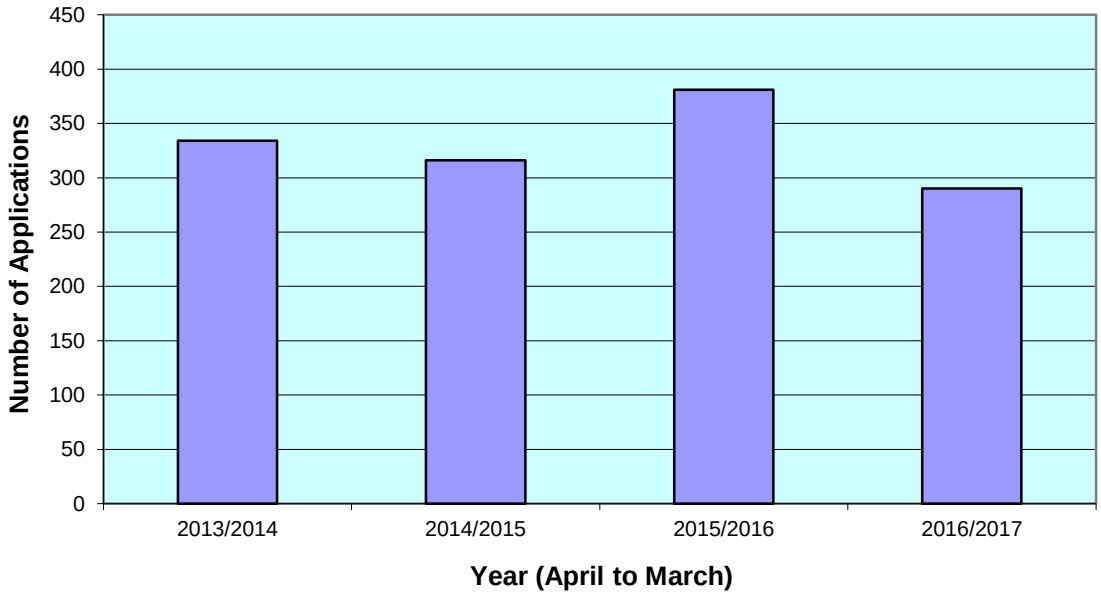


Figure1. Number of Part IX applications received over the previous four financial years.

The number of applications received each month continues to fluctuate throughout the year. Figure 2 shows the numbers of applications received month-by-month and makes comparison with the data from previous financial years. During 2016-2017, the average number of applications received per month was 24 which is lower than last year when the average was 32 applications per month.

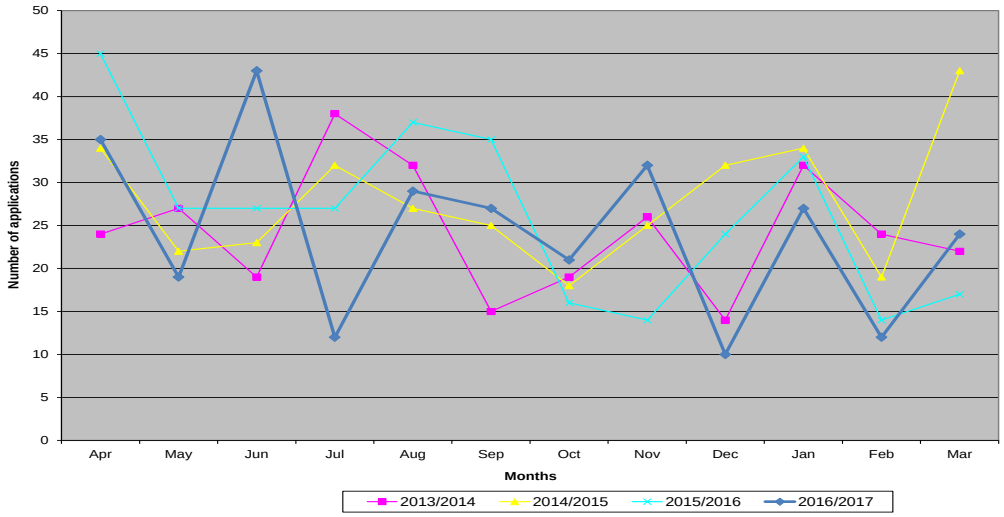


Figure 2. Number of Part IX applications received each month over the previous four financial years.

Table 1 shows a breakdown of the types of applications received during 2016-2017 compared to the previous year. The percentage of the total applications for "new" products is similar at 9% during the past year. The percentage of "me-too" products has decreased to 65% from 80% and the percentage of "line extension" products has increased from 10% to 26% compared with 2015-2016. The evaluation of "new" products is often more complex and time consuming than applications for line extensions or products where similar products are already listed ("me-too" products). These can require prolonged correspondence with the applicant as the necessary information is collated. Increased workload is also associated with a "me-too" product where the applicant requests a higher price for similar items currently listed in Part IX. This increased cost request has to be justified by the applicant resulting in the application being more complex due to increased negotiation. These factors need to be considered alongside the total number of applications received in order to fully consider the workload associated with the application process for 2016-2017.

Application type	Applications received 2013-2014	Applications received 2014-2015	Applications received 2015-2016	Applications received 2016-2017
"New" products	19(6%)	30(10%)	38(10%)	26(9%)
Line extensions	44(13%)	14(4%)	40(10%)	74(26%)
"Me too" products	271(81%)	272(86%)	303(80%)	190(65%)

Table 1. Summary of the types of applications received during 2016-2017 compared with the previous three years. ("New" products are those where no similar products have been listed in the Drug Tariff before; Line extensions are extensions to existing ranges in the Drug Tariff; "Me-too" products are products where similar products are already listed in the Drug Tariff)

A summary of the status of all applications received and processed in 2016-2017 is provided in Table 2.

APPLICATIONS RECEIVED 2016-2017	290*
Approved	218**
Rejected	4**
Withdrawn by company	7**
Pending / On Hold	111***

Table 2. Summary of applications received approved, pending and rejected in 2016-2017.

(* the applications received refer to those logged between 1st April 2016 and 31st March 2017; ** the figures for approved, rejected and withdrawn refer to all applications processed between 1st April 2016 and 31st March 2017, which includes some carried over from the previous financial year. Therefore the sum of the approved, rejected, withdrawn and pending does not equal the total applications received in 2016-2017; *** the number of pending/on-hold applications is correct as of the 31st March 2017)

The number of applications withdrawn by the applicant during 2016-2017 has decreased slightly compared with last year. NHS Prescription Services continues to review applications where no response has been received from the applicant for 6 months to ensure that all applications are current. Four applications were rejected during 2016-2017.

There were 111 applications pending or on hold as of 31 March 2017. On average 49% of "me-too" /line extensions could be processed first time, without requesting further

information from the applicant. This has decreased from 59% last year. Of the applications that could not be assessed first time incorrect certificates are the main area where an applicant needs to be contacted and insufficient information to support cost effectiveness is accounts for 28% of requests.

- 48% of requests regarding documentation are due to the 'declaration of conformity' certificate not being provided
- 20% were due to applicants not providing confirmation as to which member state of Europe the product is registered in
- 32% due to no or incorrect notified body certificates
- 28% of "me-too"/ line extensions required requests for additional information to support a premium price. This also still remains the main reason that applications remain pending for a long period of time
- 20% of requests related to problems with the samples of the products. Most commonly applicants either do not provide the correct sample of the product or they do not provide the packaging/ label of each of the variants they are applying for (e.g. each different size of dressing)

NHS Prescription Services approved 218 applications for products to be listed in Drug Tariff Part IX during 2016-2017. Figure 3 shows the number of applications received in each month against those that have subsequently been approved. The gap between the lines represents those that have been withdrawn or that are pending or on-hold.

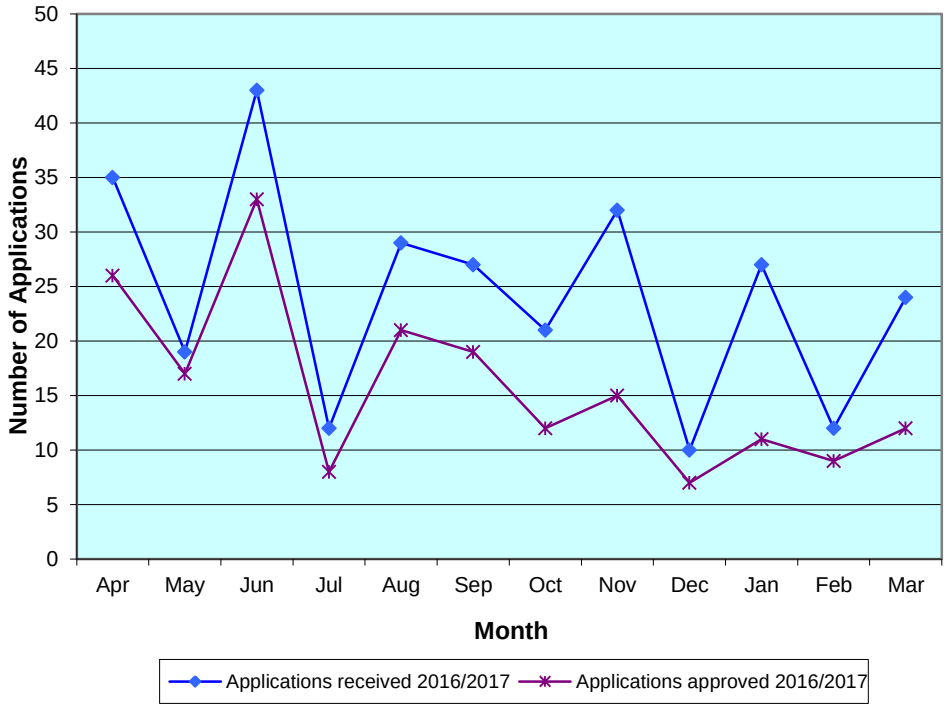


Figure 3. Number of Part IX applications received during 2016-2017 *vs* those that have subsequently been approved.

There was one appeal made against the decision by the NHS Prescription Services not to list a product. The appeal process was carried out in line with the published guidance and the decision made by NHS Prescriptions Services was upheld.

4. PART IX Prices

The mechanism to allow annual price rises to products listed in Part IX is set out in Annex D to the Drug Tariff Part IX Guidance Notes and is an agreement between the Department of Health and the Drug Tariff Part IX Forum. Manufacturers are required to give two months' notice before the publication deadline of the Drug Tariff in which the price rise will take effect, and a formula related to the Gross Domestic Product (GDP) forecast is applied to all requests. Requests for a price increase greater than that permitted by the pricing mechanism can only be approved if special circumstances prevail (and this follows a separate procedure for exceptional price increase requests). There were 10 enquiries regarding exceptional price increases for the period April 2016 to March 2017 and one of these was approved according to the criteria outlined in the procedure relating to exceptional price increases.

Figure 4 illustrates the change in the number of price increase requests that have been processed for Part IX products. 73 manufacturers submitted 169 price change requests resulting in a total of 33,919 price changes in the period April 2016 to March 2017. This is a 5% increase on the previous year. Figure 5 shows the number of price increases processed for each edition of the Drug Tariff. The figure for June was the highest at 15,486 price increases, then October at 4,945 and May the third highest at 4,909. The price rises for June account for 46% of the amount that were implemented in the whole period of 2016-17; and were predominantly for ranges of lymphoedema garments.

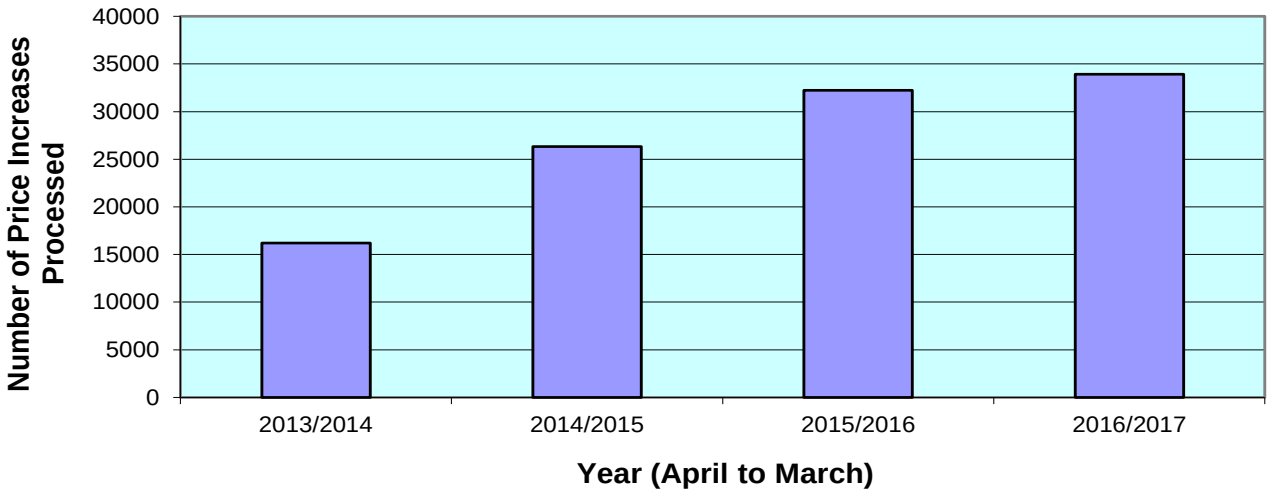


Figure 4. Number of price increases processed for Part IX appliances and chemical reagents for the previous four financial years

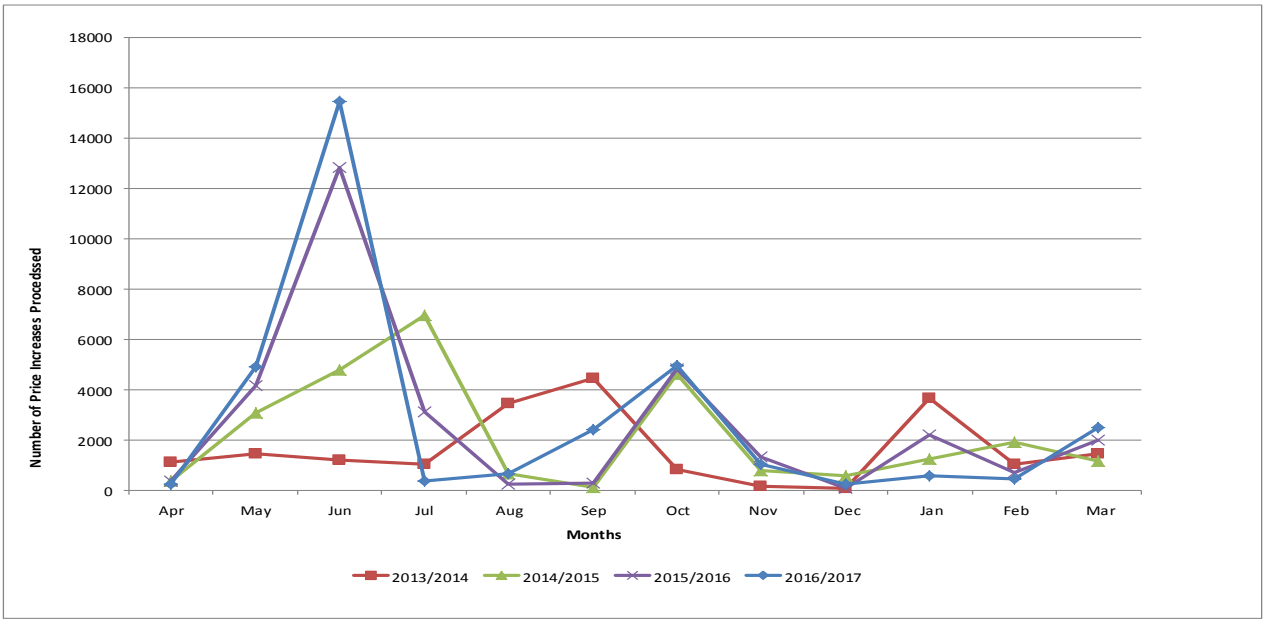
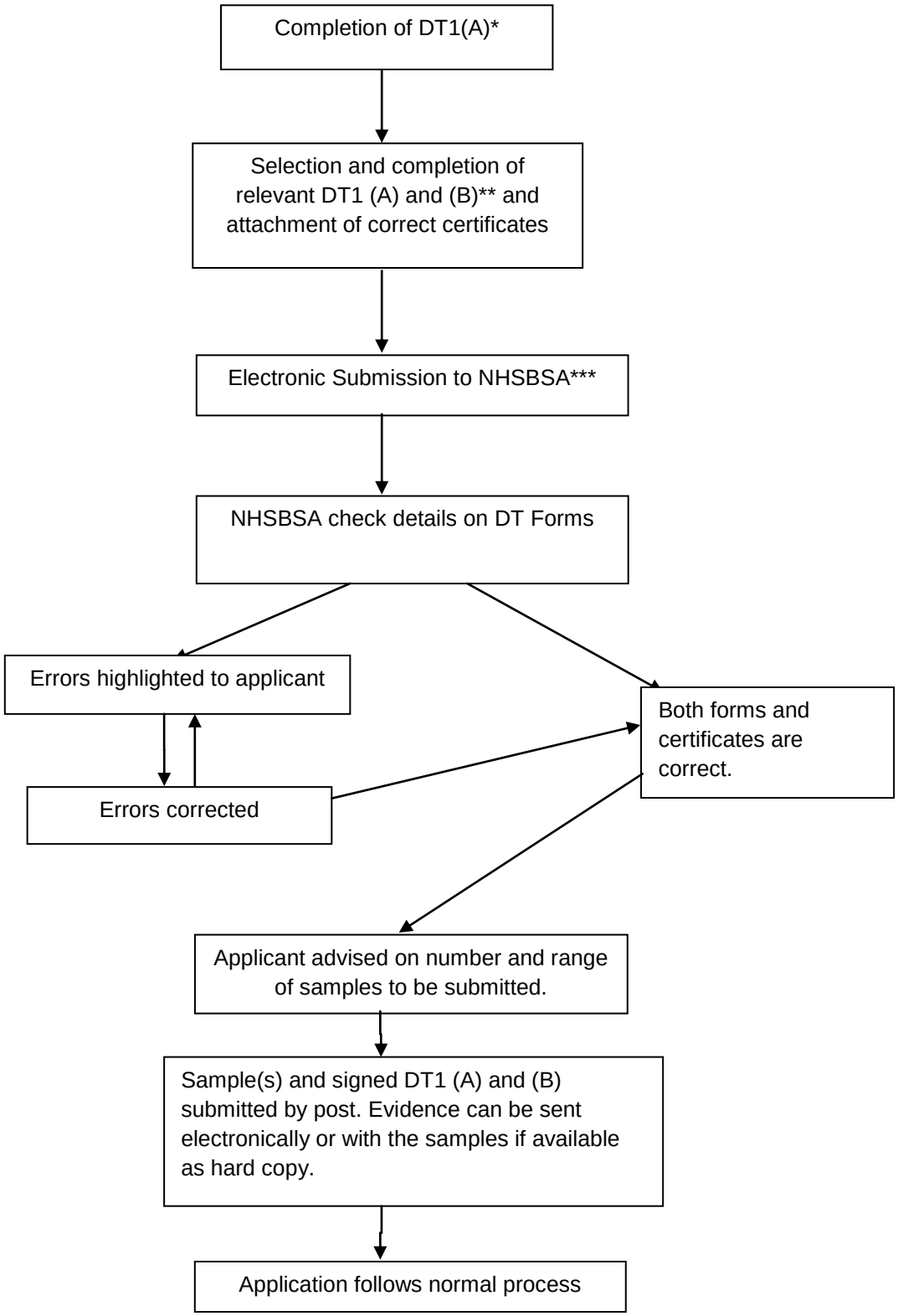


Figure 5. Number of Part IX price increases processed for each Drug Tariff edition over the previous four financial years.

5. Part IX Application Process

Figure 6 outlines a process map for making (applicants) and handling (NHS Prescription Services) Part IX applications. The aim of the application process is to provide efficient handling of applications whilst providing greater transparency to applicants making it clearer when they have not submitted the correct certification for their product and when the application has not been formally accepted into the process. It also reduces wastage and cost through tailored advice regarding sample submission.

Figure 6. Part IX application process



* Drug Tariff Application Form that is required for all Part IX applications. ** Drug Tariff Application Form specific to the class of device of the product being applied for. ***Paper submissions will also be accepted. However this will increase the lead time to processing of the forms.