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Regulatory Documents Required to Obtain Approval of Importing Diagnostic Kits to China

1. **Diagnostic kits classification guideline**
2. **Diagnostic kits clinical trial requirement**
3. **Document list required for importation of diagnostic kits**
4. **Detailed requirements**
5. **Regulatory filling flow chart**

NovoTek Therapeutics Inc.

1. Classification of Diagnostic kits

According to the risk factor, diagnostic kits are categorized into 3 classes, Class I, Class II and Class III The classification rational is shown as below:

Class III: Diagnostic kits to be used to

1. Diagnose pathogenic pathogen antigen, antibody and/or nuclear acid
2. Diagnose blood type, and tissue compatibility;
3. Test human gene related information
4. Test genetic diseases;
5. Relevant to anesthetics drug, psychotropic drugs or toxic medical drug test agent,
6. Test drug targeted receptors
7. Tumor labeling related tests
8. Drug allergy related test

Class II: Diagnostic kits to be used to

1. Protein test
2. Glucose test
3. Hormone test
4. Enzyme test
5. Lipid test
6. Vitamin test;
7. Inorganic ion test
8. Drug metabolism test
9. Self-antibody test
10. Test for other physiological, immune or biochemistry parameters
11. Other test that is not belongs to either Class I or Class III

Class I: Diagnostic kits to be used to

1. Medium (medium for bacteria and drug allergy is not included);
2. Sample operation agent including dyes, PH adjusting agent etc.

2. Diagnostic kits clinical trial requirement

（1）Class III：no less than 1000 test/ product

（2）Class I: no clinical trial required

* Diagnostic kits based on new technology (no similar products that have been approved on Chinese market, or bearing new clinical methodology should follow the requirement of Class III)

3. Document list required for importing Diagnostic kits to China

	Class III	Class II	Class I
1.Application form	√	√	√
2. Certifications	√	√	√
3.Executive Summary of Products	√	√	√
4.Product label and indications	√	√	√
5.The quality control standard and supporting documentations	√	√	√
6.3 batches test report (need to be done in China)	√	√	×
7.Main active raw material summary	√	△	△
8.Manufacturing process/ reaction system overview	√	△	△
9.Prodcut performance overview	√	√	△
10 . Supporting data on determination of accuracy and specificity errors	√	√	△
11.Stability study report	√	√	△
12.Clinical trial study report	√	√	×
13.Manufacturing and QC report	√	√	√
14.Label and indication sheet samples	√	√	√
15.Manufacturing and quality control system report	√	√	△

√： Documents need to be submitted at the time of application

△：Documents do not need to submitted at the time of application, but need to be kept in file when site inspection is processed

×：not required.

* From above list, the 3, 7, 8, 10, 11, 13 items can be completed in manufacturer's country and is not required to be repeated in China.

4. Detailed requirement

1. Registration application form

2. Certificates

The certificates should at least include the following items:

（1）Qualification certificate of the manufacturer to be allowed to manufacture medical device or diagnostic kits by government entity of its original country

(2) Regulatory approval document to allow the sales of the intended product in its original country. (For the products that don't need obtain medical appliance Marketing authorization, should supply the certificated document that demonstrates the product is not managed as a medical appliance registration and Certificated document of the product to sale legally in the country of origin.)

(3)The document that can demonstrates that the manufacturer's manufacturing system and other quality control system have passed the < Production quality management standard> of Countries of its origin.

All above three items can be hard copies, but must be signed by the government officers or Notarized by the local notary organization.

(4) Authorization letter to designated business agency (e.g. a company will be in charge of the distribution of this product in China) in China, and this agent's business license copy.

（5）If the registration procedure is authorized to a third party, an authorization letter and the copy of the Registration agency's business license is required.

3. Executive summary of the product

Should include the following items:

(1)The expected use of the product, the background of the clinical indications for the expected use, main patient population and comparison of the technology between this product and similar products already on the market.

(2)descriptions of the product including the test theory, preparation method of the main active material, the manufacturing process, preparation method of the standard and control material that is used in the quality control system.

(3)Bio-safety overview: if the product contains material from tissue or tumor of animal, pathogens or human, it is required to demonstrate that the product is safe during transportation and end user process. Any supporting data available that can demonstrate its bio-safety should be summarized in this section.

（4）Summary and evaluation of the both in vitro, in vivo and human studies results during this product development.

(5) Detailed summary on similar products current on oversea market. All supporting literature of the development of this product and relevant theory.

4. Product label and indications

The original text of product label and any insert sheet (approved by original country) and the Chinese translation. The product label should contain product names including its common name ,trade name and English name.

5. The quality control standard and supporting documentations

Provide full methodology involved in the process of final product quality control system. Also the methodology determination and development should be explained and necessary supporting literature or data for the method development should be provided in this section.

6. 3 batches test report

3 batches test report which is provided by the Inspection agencies that recognized by the SFDA.

7. Main active raw material summary

The main raw material include: antigen, antibody, quality control standards. This part should include the selection and preparation of all above materials and any related supporting data and literatures.

8. Manufacturing process/ reaction system overview

The main production technology and the research materials of the reaction system. The reaction system demonstration should include the proposed sample collection method, preparation method, calibration method(if applicable) and relevant supporting data. The standard calibration procedure should also be included in this section.

9. Analysis and performance evaluation materials

As a general rule, Analysis and performance evaluation includes the sensitivity of analysis, analytical specificity, detection range, and the accuracy of the test, the error within and between batches.

The results of the analysis and performance evaluation are important for making product standards. The developers should adopt batches of products to evaluate the performance of the above items. By analyzing the results of the analysis and performance evaluation statistically, applicant should be able to demonstrate that the established system is able to ensure the production technological process and the consistency in products' quality can be controlled effectively.

If there are different packing specification during an application for registration, or the product applies To different machine types, it is necessary to provide each packing specification product, or prepare the test data of the above items evaluation on different machines.

10. Supporting data on determination of accuracy and specificity errors

11. The stability research data

Including the stability research data of at least three batches of samples which are preserved after the validity of finished product under actual storage condition. Acceleration destructive test data should be supplied when necessary.

12. Clinical trial study report

The clinical trials should be repeated in China. The number of test required is determined by specific product.

The applicant should also provide following clinical trials material.

(1) The clinical trials material which finished overseas or the final report of the clinical use overseas.

(2) The clinical trials reports finished in China

(3) Appendix :The details of the clinical trials, including the results of all the clinical trials, other test methods information that has been used in the clinical trial (e.g. controls).

13. Manufacturing and QC report

Providing the copy of the production and self-inspection record of three continuous batches of products.

14. Label and indication sheet samples

The label on product out packing should include common name (in the same area, common name, trade name and the English name can be labeled), manufacturer's name, the information of batch No. and the indications.

The indication sheet should following SFDA regulations, which is very similar to US and Europe standard.

If the kit contains more than one major components (such as washing fluid, more than one agents), then specific information of each specific component must be also included in the indication sheet and labels.

15. Manufacturing and quality control system report

In this section, please provide any certificate that manufacturer has obtained from oversea regulatory offices to demonstrate the capability of this product's manufacturing and quality control system.

5. Application procedure and turn around flow chart: