SECTION II SECTION 2

Basis for ANDA Submission

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(Overall ANDA Guideline Requirements for this Section).

2.O Section Page and Title. The information in this section summarizes the four critical structures supporting the legal basis for this abbreviated new drug application

2.1.0 Basis for ANDA Submission is submitted as follows and is;

2.1.1 Based on an Abbreviated New Drug Application

or

2.1.2 Based on an approved ANDA Suitability Petition

and

3.0 Based on Active Ingredient (same as RLD) and current approved labeling

and

4.0 Based on Route of Administration, Dosage Form and Strength

and

5.0 Based on Bioequivalency Data submitted (Applicant Generic Drug vs. RLD)

NOTE:-
MODEL Letters are provided in Section IV highlighting each of four critical structures and supporting documentation stating the legal basis for this abbreviated new drug application

SECTION II SECTION 2

Basis for ANDA Submission

BASIS FOR ABBREVIATED NEW DRUG APPLICATION

[a] Listed Drug.

This applications refers to the Reference Listed Drug [NAME] ❑Tablet / ❑Capsule manufactured by **[RLD Company Name Inc. / Ltd.]**.

The basis for **[Applicant Company Name Inc. / Ltd.]** proposed ANDA for Full **Generic Drug Name** is the approved reference listed drug as above, the subject of ANDA [#00 0000] held by **[RLD Company Name Inc. / Ltd.]**. and containing **[000.0 / 000.0 / 000.0mg] of [Generic Drug Name].**

According to the FDA listed information published in the list of approved Drug Products known as the Orange Book 20th (2000) Edition the listing is enclosed herewith.

[b] Exclusivity.

Furthermore according to the FDA listed information published in the list of Approved Drug Products [Orange Book] 20th (2000) Edition the RLD is entitled to a period of marketing exclusivity (under section 505j[4][D] of the Act as a New Chemical Entity until the NCE's expiration period of **MM/DD/YY**

or

Furthermore according to the FDA listed information published in the list of Approved Drug Products [Orange Book] 20th (2000) Edition, **no** exclusivity's for the listed the RLD applies.

[c] According to the information published in the 20th Edition List (2000), the reference listed drug is covered by **[one / two]** use patent which is addressed in Section III of this application.

[d] APPROVED ANDA SUITABILITY PETITION

The basis for **[Applicant Company Name Inc. / Ltd.]** proposed ANDA is further based on the approval of the suitability petition pursuant to the 21 Code Federal Register (CFR) # 505[j][2][c] and 21 CFR 314.93 that requested a change from the above listed drug in subparagraph 1[a] as above.

Docket No **[00000]**

The basis of this ANDA SUITABILITY PETITION is held and was submitted under Docket No **[00000]** and approved on **MM/DD/YY.**

A copy of the FDA letter approving the ANDA SUITABILITY PETITION is attached in section II of this application (page **[00]**)

Basis for ANDA Submission

BASIS FOR ABBREVIATED NEW DRUG APPLICATION (continued)

ACTIVE INGREDIENT **[00000]**

21 CFR 314.94 [A][5][i]

The active ingredient of **[Applicant Company Name Inc. / Ltd.]** **Generic** ❑Tablet / ❑Capsule is the same as that of the **RLD brand name**

We refer the reviewer to **[Applicant Company Name Inc. / Ltd.]** annotated labeling and the current approved labeling of the RLD as shown in Section IV-05 of this ANDA (Refer pages **[00] to [00]**)

ROUTE OF ADMINISTRATION DOSAGE FORM AND STRENGTH

21 CFR 314.94 [A][5][i]

The Route of Administration, Dosage Form and Strength **[Applicant Company's Name Inc. / Ltd.]** **of Generic** ❑Tablet / ❑Capsule is the same as for [**RLD brand name**]

Again we refer the reviewer to **[Applicant Company Name Inc. / Ltd.]** annotated labeling and the current approved labeling of the RLD as shown in Section IV-05 of this ANDA (Refer pages **[00] to [00]**)

BIOEQUIVALENCY DATA **[00000]**

21 CFR 314.94 [A][7][i]

[Applicant Company Name Inc. / Ltd.] bioequivalent study on [Generic **❑Tablet** / **❑Capsule Name**] was successfully conducted in terms of current approval parameters by Clinical Research Laboratories [Name and Address]

The Full Bioequivalence Report is attached to Section VI of this ANDA (Refer pages **[000] to [000]**)

[Signature of Responsible Person]

[Name of Responsible Person] Date

Regulatory Affairs Director

[Applicant Company Name Inc. / Ltd.]

[Signature of Responsible Person]

[Two typical examples of this section are given below]

Basis for ANDA Submission

EXAMPLE 1:

Listed Drug.
This applications refers to the Reference Listed Drug [RLD] **Imodium [1]/ Imodium [2] Generic** ❑Tablet / ❑Capsule manufactured by **[RLD Company Name Inc. / Ltd.]**[3].
A copy of the Orange Book 20th (2000) Edition listing is enclosed herewith.

According to the information published in the 20th Edition List, the reference listed drug is covered by **[☑ no / one / two]** use patent which is addressed in Section III of this application.

Exclusivity.
There are **[ONE] / [two] / ☑ [no]** exclusivity's for the listed drug.
I-184 - expires Sept 24, 2000
I-185 - expires Sept 24, 2000

[Signature of Responsible Person]
---------- ----------
[Name of Responsible Person] Date
Regulatory Affairs Director
[Applicant Company Name Inc. / Ltd.]

[Signature of Responsible Person]
---------- ----------
[Name of Responsible Person] Date
Regulatory Affairs Director
[Applicant Company Name Inc. / Ltd.]

[1]INNOVATOR NAME COUNTRY US or EU
[2]USA RLD 375 / 500 mg - Application Number 000000
[3]INNOVATOR

Basis for ANDA Submission

EXAMPLE 2:

Listed Drug.
This applications refers to the Reference Listed Drug [RLD] **Imodium[1]/ Imodium[2]** ❑Tablet / ❑Capsule manufactured by **[RLD Innovator Company Name Inc. / Ltd.]**[3].
A copy of the Orange Book 20th (2000) Edition listing is enclosed herewith.

According to the information published in the 20th Edition List (2000), the reference listed drug [RLD] is covered by **[☑ no / one /two]** use patent(s) which is addressed in Section III of this application.

Exclusivity.
According to the information published in the 20th Edition of the Orange Guide (2000), there are **[one] / [two] / ☑ [no]** exclusivity's for the listed drug.
I-000 - expires MM DD, 2000
I-000 - expires MM DD, 2000

[Signature of Responsible Person]

---------- ----------
[Name of Responsible Person] Date
Regulatory Affairs Director
[Applicant Company Name Inc. / Ltd.]

[Signature of Responsible Person]
---------- ----------
[Name of Responsible Person] Date
Regulatory Affairs Director
[Applicant Company Name Inc. / Ltd.]

1 INNOVATOR
2 USA RLD IS REGISTERED AS STRENGTH **0** mg +**00** mg
INNOVATOR Application Number **[00000]**
3 INNOVATOR

Basis for ANDA Submission

ANDA SUITABILITY PETITION APPROVAL LETTER

Date:

Office of Generic Drugs
CDER, Food and Drug Administration
Document Control Room - No. 150
Metro Park North II
7500 Standish Place
ROCKVILLE MD 20855-2773.

ORIGINAL ABBREVIATED NEW DRUG APPLICATION
[**Generic name**] **Oral Tablets/Capsules**

Dear Sir,

We submit herewith the ANDA SUITABILITY PETITION APPROVAL LETTER for the drug product [Generic name ❑Tablet / ❑Capsule [000 / 000] mg.

[Signature of Responsible Person]
---------- ----------
[Name of Responsible Person] Date
Regulatory Affairs Director
[Applicant Company Name Inc. / Ltd.]

[ANDA SUITABILITY PETITION APPROVAL LETTER
Attached in Section XXII]

End of Section 2.