

SUBJECT:

THE SECRETARY OF STATE
WASHINGTON

**Acceptance of
Swiss Inspections**

**(FDA Agreement
Number 225-75-
4058)**

**(Previously CPG
7156d.01)**

Notes:

**The FDA contact
for this Agreement
is Gary Pierce,
HFC-130**

**Tel. No.
301-443-3276**

**This Agreement is
in effect
indefinitely.**

Dear Mr. Ambassador:

October 28, 1968

I refer to your letter of June 28 and to the Department's interim reply of July 3 regarding the discussions between representatives of our two governments on the subject of Swiss drug inspection.

As you know, a representative of the Food and Drug Administration visited Switzerland in August for the purpose of evaluating the Swiss inspection system as it applies to bulk drugs. It is our understanding that currently there is no proposal that finished dosage forms be shipped to the United States by Swiss manufacturers. The evaluation has now been completed and it has been determined that the two inspection systems are substantially equivalent. The Food and Drug Administration therefore agrees to recognize the Swiss inspection as being equivalent to the U. S. inspection. The Food and Drug Administration will, however, expect to be invited to complete or renew its evaluation in special cases which might arise, as indicated in your letter of June 28.

Sincerely yours,

/s/
Dean Rusk

His Excellency
Felix Schnyder,
Ambassador of Switzerland.

EMBASSY OF SWITZERLAND
June 28, 1968

My dear Mr. Secretary:

I refer to previous conversations between representatives of the Swiss Government and the Government of the United States regarding inspection of the production of Swiss drugs.

Since an understanding has been reached on United States acceptance in principle of Swiss drug inspections, I am now authorized, in accordance with a decision taken by my Government, to invite representatives of the Food and Drug Administration to Switzerland to proceed to the envisaged

Notes:

evaluation of the Swiss inspection systems.

The Swiss Authorities will be glad to meet the representatives of the Food and Drug Administration in Berne on August 26, 1968. I would suggest that further details be settled directly between the officials concerned in Switzerland.

I understand that, after a satisfactory evaluation has been completed, the Food and Drug Administration will recognize Swiss inspections as being equivalent to United States inspections. However, it will expect to be invited to complete or renew the evaluation in special cases which might arise, for example, in the field of steroids or antibiotics, or when significant technological advances require new inspection procedures. Please accept, my dear Mr. Secretary, the assurances of my highest consideration.

The Ambassador
of Switzerland is
currently Mr. Carlo
Jhemetti

The Ambassador of Switzerland

_____/s/____

Felix Schnyder