GERALD J. MOSSINGHOFF

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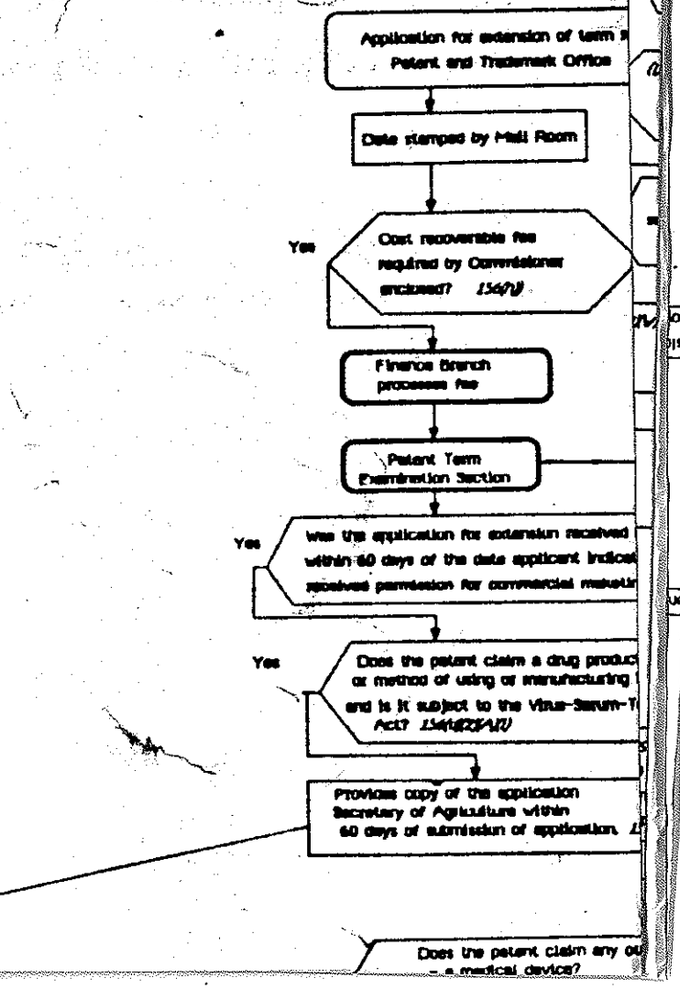
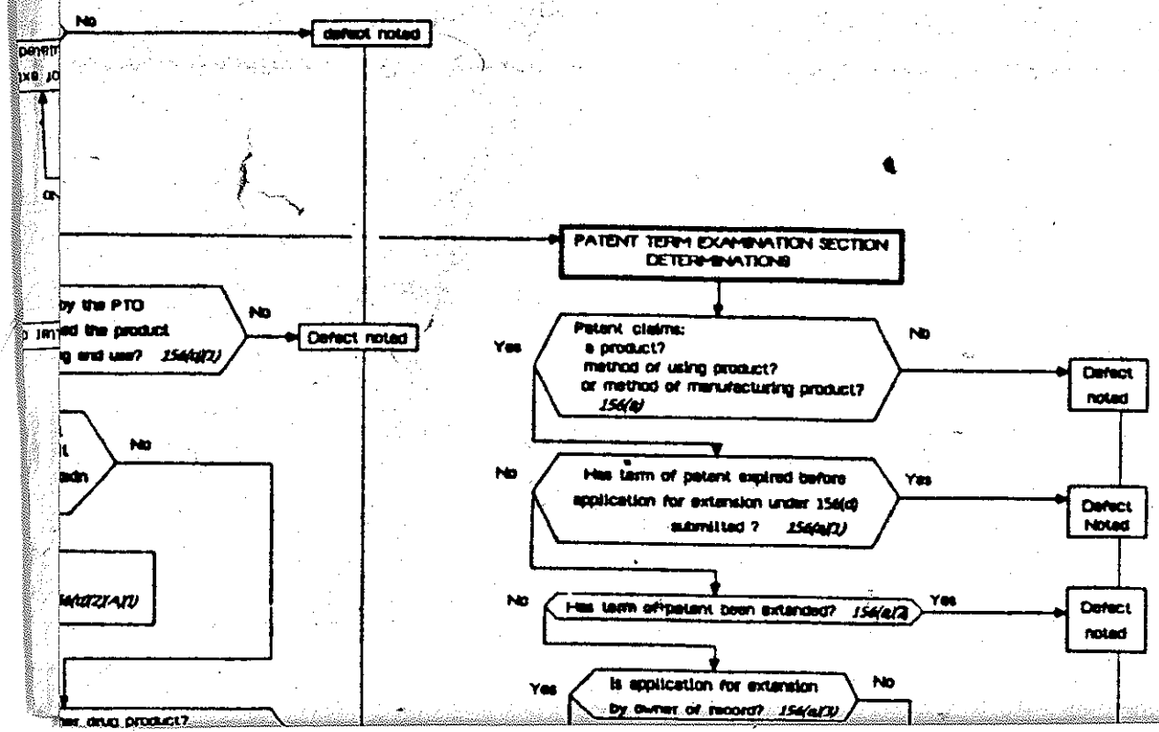
PATENT TERM E

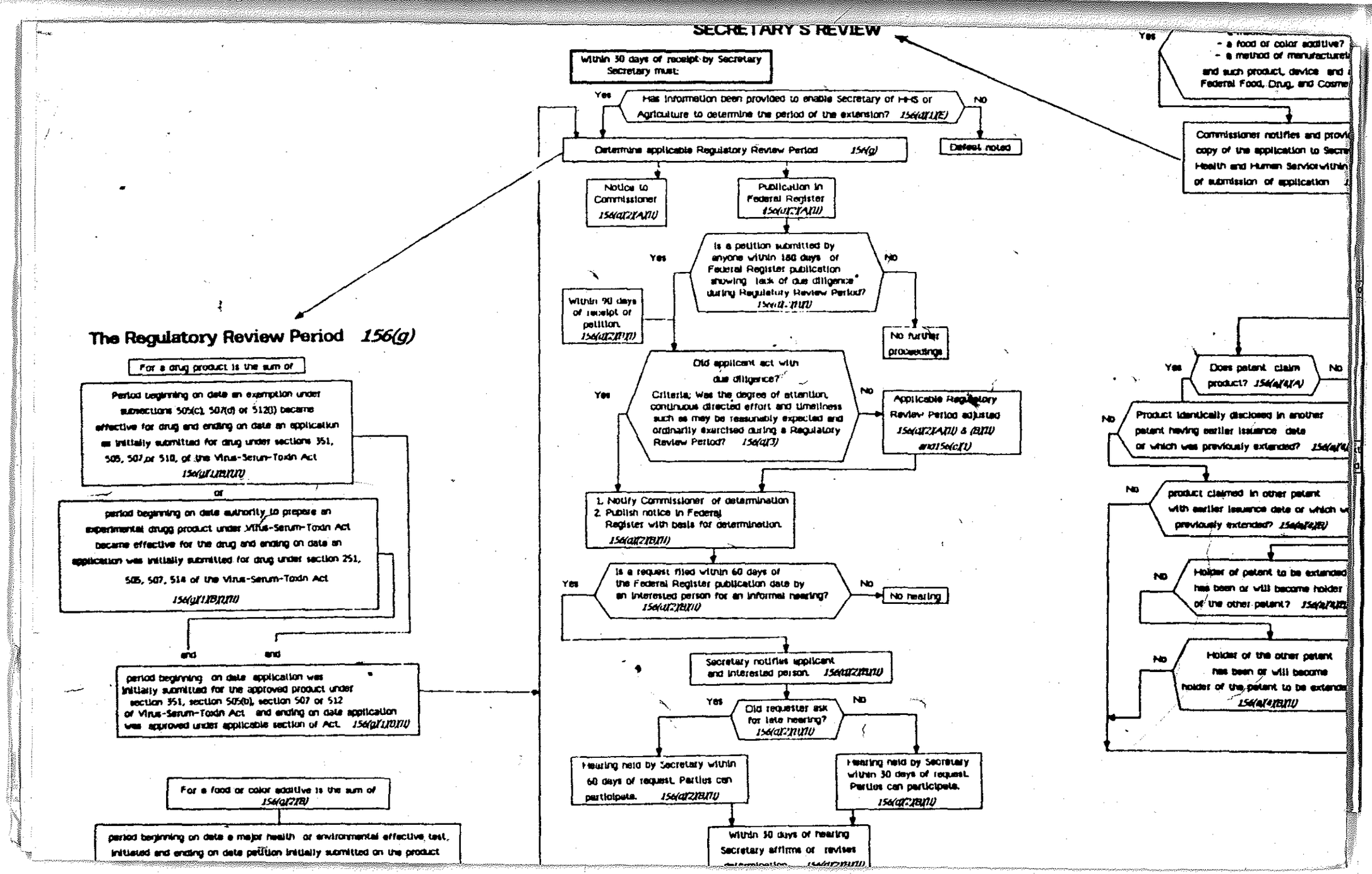
FLOWCHART OF PROCESSING

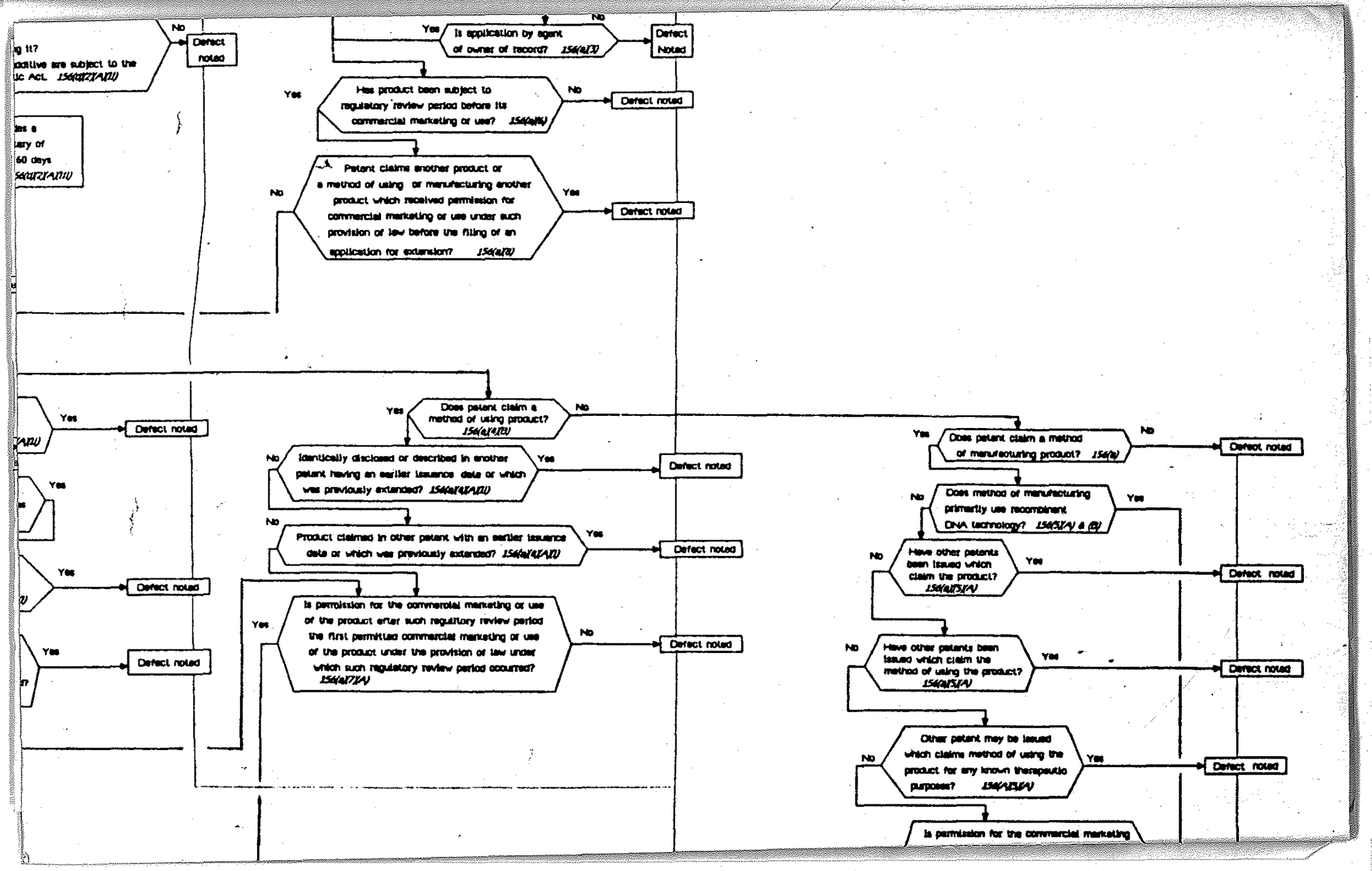


XTENSION

UNDER 35 U.S.C. 156




SECRETARY'S REVIEW
within 30 days of receipt by Secretary Secretary must:
Yes
Has information been provided to enable Secretary of HHS or Agriculture to determine the period of the extension? 156(d)(1)(E)
No
Defect noted
Determine applicable Regulatory Review Period 156(g)
Notice to Commissioner 156(d)(2)(A)(i)
Publication in Federal Register 156(d)(2)(A)(i)
Is a petition submitted by anyone within 180 days of Federal Register publication showing lack of due diligence during Regulatory Review Period? 156(d)(2)(B)(i)
Yes
No
Within 90 days of receipt of petition. 156(d)(2)(B)(i)
No further proceedings
Old applicant act with due diligence? Criteria; was the degree of attention, continuous directed effort and timeliness such as may be reasonably expected and ordinarily exercised during a Regulatory Review Period? 156(d)(3)
Yes
No
Applicable Regulatory Review Period adjusted 156(d)(2)(A)(i) & (B)(i) and 156(c)(1)
1. Notify Commissioner of determination
2. Publish notice in Federal Register with basis for determination.
156(d)(2)(B)(i)
Is a request filed within 60 days of the Federal Register publication date by an interested person for an informal hearing? 156(d)(2)(B)(i)
Yes
No
No hearing
Secretary notifies applicant and interested person. 156(d)(2)(B)(ii)
Old requester ask for late hearing? 156(d)(2)(B)(ii)
Yes
No
Hearing held by Secretary within 60 days of request. Parties can participate. 156(d)(2)(B)(ii)
Hearing held by Secretary within 30 days of request. Parties can participate. 156(d)(2)(B)(ii)
Within 30 days of hearing Secretary affirms or revises
The Regulatory Review Period 156(g)
For a drug product is the sum of
Period beginning on date an exemption under subsections 505(c), 507(d) or 512(j) became effective for drug and ending on date an application as initially submitted for drug under sections 351, 505, 507 or 510, of the Virus-Serum-Toxin Act 156(g)(1)(B)(i)(I)
or
period beginning on date authority to prepare an experimental drugg product under Virus-Serum-Toxin Act became effective for the drug and ending on date an application was initially submitted for drug under section 351, 505, 507, 514 of the Virus-Serum-Toxin Act 156(g)(1)(B)(i)(II)
and
and
period beginning on date application was initially submitted for the approved product under section 351, section 505(b), section 507 or 512 of Virus-Serum-Toxin Act and ending on date application was approved under applicable section of Act. 156(g)(1)(B)(ii)
For a food or color additive is the sum of 156(g)(2)(B)
period beginning on date a major health or environmental effective test, initiated and ending on date petition initially submitted on the product
Yes
- a food or color additive?
- a method of manufacturing
and such product, device and
Federal Food, Drug, and Cosme
Commissioner notifies and provi
copy of the application to Secre
Health and Human Service within
of submission of application
Yes
Does patent claim product? 156(a)(1)(A)
No
No
Product identically disclosed in another patent having earlier issuance date or which was previously extended? 156(a)(1
No
product claimed in other patent with earlier issuance date or which w
previously extended? 156(a)(1)(B)
No
Holder of patent to be extended has been or will become holder of the other patent? 156(a)(1)(B)
No
Holder of the other patent has been or will become holder of the patent to be extend
156(a)(1)(B)(i)


No
Defect noted
Yes
Is application by agent of owner of record? 156(a)(3)
No
Defect Noted
Yes
Has product been subject to regulatory review period before its commercial marketing or use? 156(a)(4)
No
Defect noted
No
Patent claims another product or a method of using or manufacturing another product which received permission for commercial marketing or use under such provision of law before the filing of an application for extension? 156(a)(5)
Yes
Defect noted
Yes
Defect noted
Yes
Defect noted
Yes
Defect noted
Yes
Does patent claim a method of using product? 156(a)(4)(B)
No
No
Identically disclosed or described in another patent having an earlier issuance date or which was previously extended? 156(a)(4)(A)(B)
Yes
Defect noted
No
Product claimed in other patent with an earlier issuance date or which was previously extended? 156(a)(4)(A)(B)
Yes
Defect noted
Yes
Is permission for the commercial marketing or use of the product after such regulatory review period the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred? 156(a)(7)(A)
No
Defect noted
Yes
Does patent claim a method of manufacturing product? 156(b)
No
Defect noted
No
Does method of manufacturing primarily use recombinant DNA technology? 156(5)(A) & (B)
Yes
No
Have other patents been issued which claim the product? 156(a)(5)(A)
Yes
Defect noted
No
Have other patents been issued which claim the method of using the product? 156(a)(5)(A)
Yes
Defect noted
No
Other patent may be issued which claims method of using the product for any known therapeutic purposes? 156(A)(5)(A)
Yes
Defect noted
Is permission for the commercial marketing

under the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product *156(g)(2)(B)(i)*

and

period beginning on date petition initially submitted on the product under Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product and ending on date regulation became effective or if objections were filed, on date objections resolved and commercial marketing permitted, or if marketing permitted and later revoked pending further proceedings, ending on the date proceedings resolved and commercial marketing permitted. *156(g)(2)(B)(ii)*

For a medical device is the sum of: *156(g)(3)(B)*

period beginning on date a clinical investigation on humans involving the device was begun and ending on date application initially submitted with respect to the device under section 515 *156(g)(3)(i)(I)*

and

period beginning on date application initially submitted with respect to device under section 515 and ending on date application approved under Act or period beginning on date notice of completion of product development protocol was initially submitted under section 515(f)(5) and ending on date protocol declared completed under section 515(f)(6). *156(g)(3)(i)(II)*

Limitations of the periods for a drug product, food or color additive or medical device are *156(g)(4)*

If patent issued after date of enactment, the period of extension may not exceed 5 years *156(g)(4)(A)*

If patent issued before date of enactment and
I-no exemption request submitted;
II-no experimental drug product request submitted
III-no major health or environmental effects test initiated and no petition for a regulation or application for registration submitted;
IV- no clinical investigation began or product development protocol submitted before date for approved product,
the period of extension may not exceed 5 years
156(g)(4)(B)

If patent issued before date of enactment and action in box immediately above was taken before enactment of section, or approved product and commercial marketing or use has not been approved before date of enactment, period of extension may not exceed 2 years *156(g)(4)(C)*

What is length of extension of term? *156(c) & (g)*

Extension of term is equal to the Regulatory Review Period for the approved product, which period occurs after the date the patent is issued

Except:

1. The extension is reduced by any period during which applicant for extension did not act with due diligence as determined under 156(d)(2)(B).
2. After reduction under (1.), the extension shall include 1/2 of the time in periods in
   - 156(g)(1)(B)(i)
   - 156(g)(2)(B)(i)
   - 156(g)(3)(B)(i)

156(c)(1)-(2)

Commissioner notified

Published in Federal Register

Yes — Is the approved product identified? *154(d)(1)(A)* — No → Defect noted

Yes — Is the patent to be extended identified? *154(d)(1)(B)* — No → Defect noted

Yes — Is each patent claim for the approved product or method of using or manufacturing it identified? *154(d)(1)(B)* — No → Defect noted

Yes — Does the application comply with the disclosure requirements of the Commissioner? *154(d)(4)* — No → Defect noted

Yes — Does the patent owner state that each other patent known which:
1. claims, or
2. identically discloses or
3. describes
the approved product or method of using or manufacturing it is identified? *154(d)(1)(C)* — No → Defect noted

Yes — Does the patent owner state that all other products which have received permission for commercial marketing or use and which are claimed in patents noted in the previous box are identified? *154(d)(1)(D)* — No → Defect noted

Yes — Does the patent owner provide information under 156(a) and (b) to enable determination of
-- eligibility for extension and
-- rights derived therefrom? *154(d)(1)(E)* — No → Defect noted

Yes — Does the patent owner provide information to enable the Secretary of Agriculture or HHS to determine period of extension under 156(g)? *154(d)(1)(F)* — No → Defect noted

Yes — Is a brief description of activities undertaken during Regulatory Review Period with respect to approved product and significant dates given? *154(d)(1)(F)* — No → Defect noted

Yes — Is all patent and other information required by Commissioner provided? *154(d)(1)(G)* — No → Defect noted

Letter containing

review period the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review occurred? *156(a)(7)(A)* — No → Defect noted

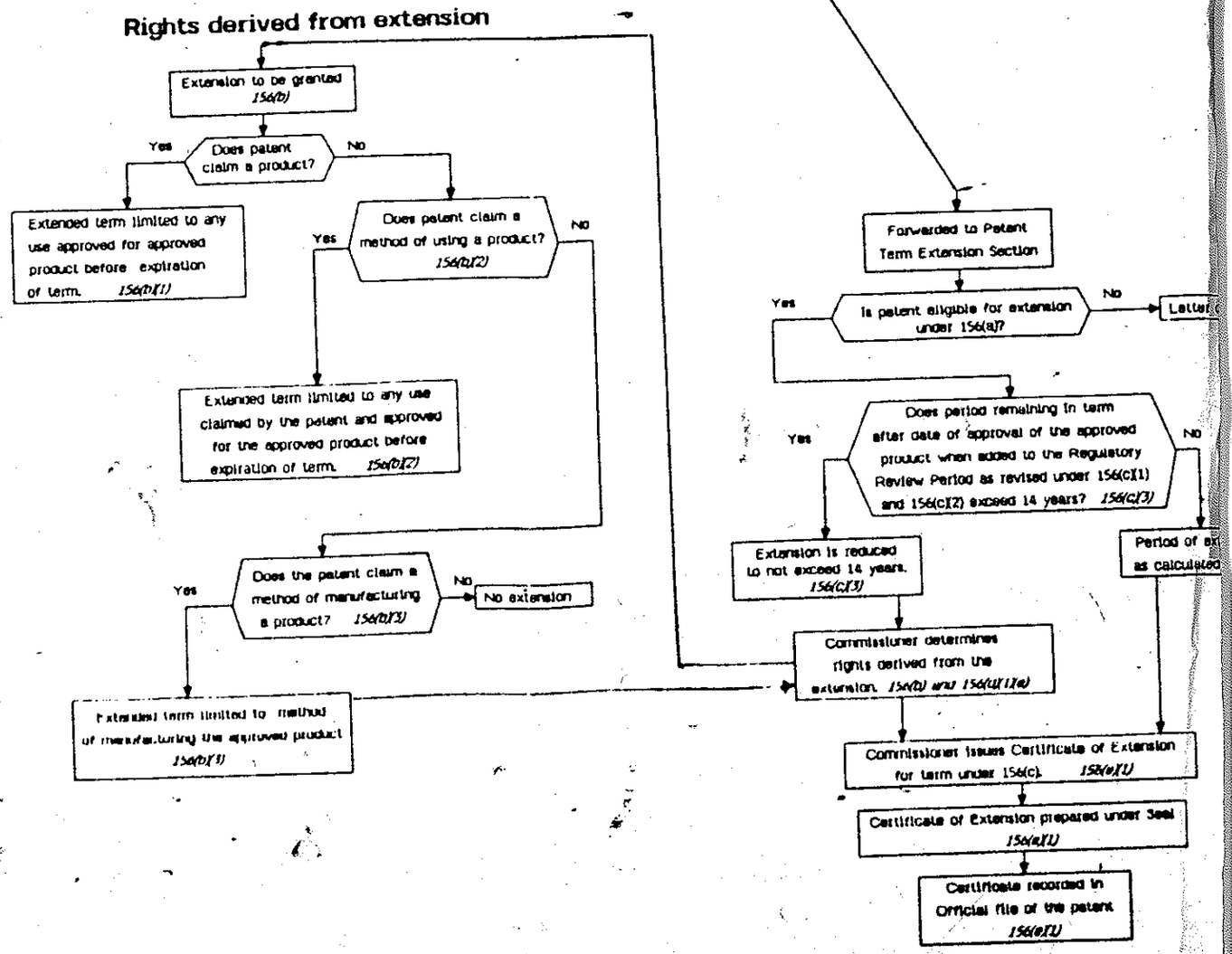
No — Is another method of manufacturing the product primarily using recombinant DNA technology claimed in a patent having an earlier issuance? *154(a)(5)(ii)(I)* — Yes → Defect noted

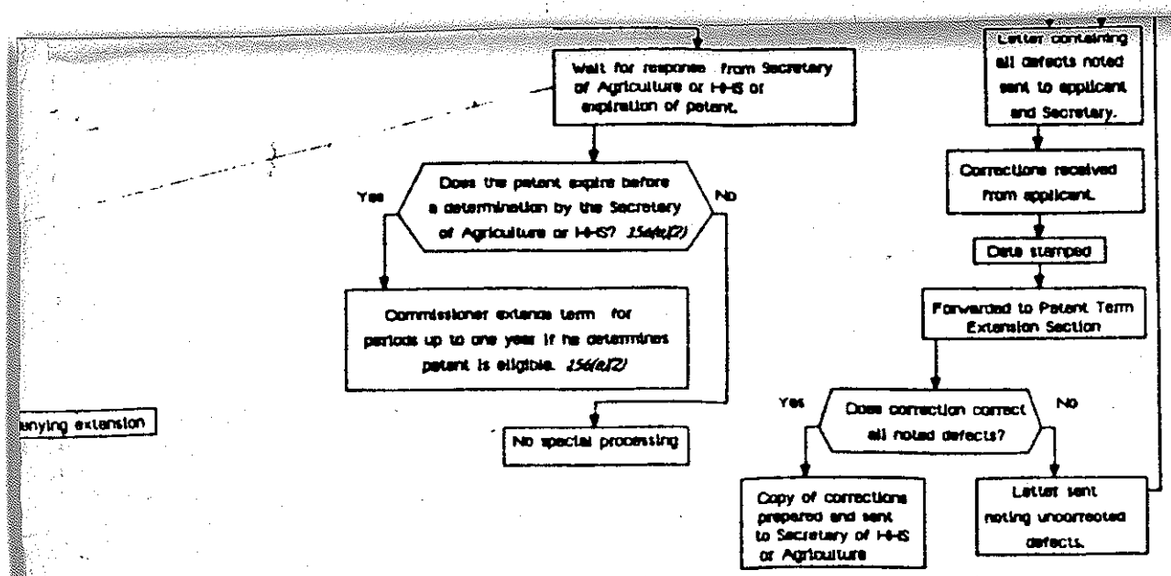
No — Is there a patent for the product or for a method of using the product? *154(a)(5)(ii)(I)* — Yes

No — Is that patent held by the holder of the patent for the method of manufacturing? *154(a)(5)(ii)(I)* — Yes → Defect noted

No — Is holder or person who controls the holder of that patent owned or controlled by the holder of the patent for method of manufacturing the product? *154(a)(5)(ii)(II)* — Yes → Defect noted

Yes — Is permission for commercial marketing or use of the product after such Regulatory Review Period the first permitted marketing or use of a product manufactured under the process claimed in the patent? *154(a)(7)(B)* — No → Defect noted


Rights derived from extension
Extension to be granted
156(b)
Does patent claim a product?
Yes
No
Extended term limited to any use approved for approved product before expiration of term. 156(b)(1)
Does patent claim a method of using a product? 156(b)(2)
Yes
No
Extended term limited to any use claimed by the patent and approved for the approved product before expiration of term. 156(b)(2)
Does the patent claim a method of manufacturing a product? 156(b)(3)
Yes
No
No extension
Extended term limited to method of manufacturing the approved product 156(b)(3)
Forwarded to Patent Term Extension Section
Is patent eligible for extension under 156(a)?
Yes
No
Does period remaining in term after date of approval of the approved product when added to the Regulatory Review Period as revised under 156(c)(1) and 156(c)(2) exceed 14 years? 156(c)(3)
Yes
No
Extension is reduced to not exceed 14 years. 156(c)(3)
Commissioner determines rights derived from the extension. 156(b) and 156(d)(1)(a)
Commissioner issues Certificate of Extension for term under 156(c). 156(a)(1)
Certificate of Extension prepared under Seal 156(a)(1)
Certificate recorded in Official file of the patent 156(a)(1)



enying extension

ension
above.