

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

017697Orig1s027

Trade Name: Kinevac

Generic or Proper Name: Sincalide for Injection

Sponsor: Bracco Diagnostics Inc.

Approval Date: February 17, 2016

Indication: (1) to stimulate gallbladder contraction, as may be assessed by various methods of diagnostic imaging, or to obtain by duodenal aspiration a sample of concentrated bile for analysis of cholesterol, bile salts, phospholipids, and crystals; (2) to stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology; (3) to accelerate the transit of a barium meal through the small bowel, thereby decreasing the time and extent of radiation associated with fluoroscopy and x-ray examination of the intestinal tract.

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APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17697/S-027

APPROVAL LETTER

Bracco Diagnostics Inc.
Attention: Melanie Benson
Director, US Regulatory Operations
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831

Dear Ms. Benson:

Please refer to your Supplemental New Drug Application (sNDA) dated August 20, 2015 and received August 21, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kinevac® (sincalide) for Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides a correction of the structural assignments for four known sincalide-related impurities (HPLC peaks (b) (4) in the Jubilant HollisterStier (b) (4)).

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81

If you have any questions, call Laya Keyvan, Regulatory Project Manager, at (240) 402-4598.

Sincerely,

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

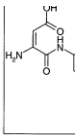
David Lewis, Ph.D., OPQ/OLDP/DPMA1/BII, signing for Hasmukh Patel, Ph.D.,
DD/OPQ/OLDPMA

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APPLICATION NUMBER:

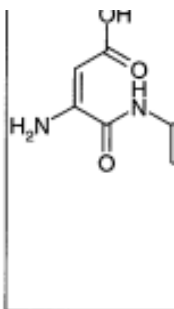
017697Orig1s027

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW # 1		1. ORGANIZATION	2. NDA NUMBER 17-697/S-027 CBE-30
3. NAME AND ADDRESS OF APPLICANT (City and State) Bracco Diagnostics Inc 259 Prospect Plains Road, Building.H- Monroe Twp. NJ 08831		4. AF NUMBER	
		5. SUPPLEMENT(S) NUMBER(S) DATES(S) Letter date: 9/14/15 Received date: 9/15/15 Goal Date: 2/21/16	
6. NAME OF DRUG: Kinevac® Injection	7. NONPROPRIETARY NAME Sincalide for injection		
8. SUPPLEMENT PROVIDES FOR: Change in the drug product specification with regard to impurities in the lyophilized drug product.		9. AMENDMENT(S), REPORT(S), ETC. NUMBER(S) DATE(S)	
10. PHARMACOLOGICAL CATEGORY Stimulation of gallbladder and pancreatic secretion through the small bowel	11. HOW DISPENSED RX <u> X </u> OTC		12. RELATED IND/NDA/DMF
13. DOSAGE FORM(S) Injection, solution	14. POTENCY 5 mcg		
15. CHEMICAL NAME AND STRUCTURE 		16. RECORDS AND REPORTS CURRENT YES <u> </u> NO <u> </u> REVIEWED YES <u> </u> NO <u> </u>	
17. COMMENTS: On the basis of recent MS/MS studies, the structural identities of two pairs of known sincalide-related impurities have been corrected . There has been no change in the impurity profile, and there is no change in the limit for any HPLC peak. Other than the correction of the structural assignments of the peaks, there is no other change in the specification.			
18. CONCLUSIONS AND RECOMMENDATIONS: From CMC standpoint, this supplement is recommended <u>for approval</u> . cc: Orig. NDA 17-697/S-027 doc # N:\NDA\17-697\S-027\Chem\02/13/16. REV			
19. REVIEWR NAME: Hossein S. Khorshidi	SIGNATURE		DATE COMPLETED 2/13/2016

Background

This CBE-30 supplement provides for a change in the drug product specification with regard to impurities in the lyophilized drug product.



Sincalide

Review Note

On the basis of recent MS/MS studies, the structural identities of two pairs of known sincalide-related impurities **have been corrected**. (b) (4)

Initial Quality Assessment - OLDP Division of Post-Marketing Activities I

NDA: 17-697	NME: Yes <input type="checkbox"/> No <input type="checkbox"/>	Original NDA Approval Date:
Supplement: S-027	Applicant: Bracco	Product: Kinevac® (sincalide for Injection)
Clinical Division: DGIEP		
Managed by: OND <input type="checkbox"/> Efficacy <input type="checkbox"/> Labeling <input type="checkbox"/>		OPQ <input checked="" type="checkbox"/>
Receipt Date: 8/20/2015 plus amendment of 9/14/2015		PDUFA Goal Date: 2/20/2016
Proposed changes: correction of error in individual impurity limit for "peak 6" as included in 17-697 S-025		
Submitted as: Paper <input checked="" type="checkbox"/> Electronic <input type="checkbox"/> PDF version scanned by OPRO RBPM		Complete Response: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Previous Reviewer:
Submitted Category: CBE-0 <input type="checkbox"/> CBE-30 <input checked="" type="checkbox"/> PA <input type="checkbox"/>		Final Category: CBE-0 <input type="checkbox"/> CBE-30 <input checked="" type="checkbox"/> PA <input type="checkbox"/>
Expedited Review Requested: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Drug Shortage: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Bundled Supplements: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Facility Entry/Consults Needed: Facility Entry: <input type="checkbox"/> Micro: <input type="checkbox"/> Biopharm: <input type="checkbox"/> Pharm/tox: <input type="checkbox"/> Statistics: <input type="checkbox"/> CDRH: <input type="checkbox"/> OPF: <input type="checkbox"/> DMEPA: <input type="checkbox"/> Other:		
DMF Review: <input type="checkbox"/>		
Comments: The supplement S-027 (paper copy, but also scanned by OPRO RBPM) corrects a drug product specification for a specified impurity: <div style="background-color: #cccccc; height: 100px; width: 100%; margin-top: 10px;"></div> <p style="text-align: right;">(b) (4)</p> <p>The amendment of 9/14/2015 provides a correction to the chemical structures for two sincalide-related impurities (b) (4)</p> <p>The specified limits are not changed (with the exception of the correction listed above for the original NDA 17-697 S-027).</p>		

QAL: David Lewis	Date: 12/22/2015
Assigned Reviewer: Hossein (Shawn) Khorshidi	RBPM: Laya Keyvan