The FDA as Gatekeeper
Premarket Review of Tobacco Products

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Overview

- Premarket Review Under the TCA
- Implementation of Premarket Review 2009-2016
  - FDA's Review Priority
  - Deficient Applications
- Solutions to Problems

Premarket Review Under the TCA

Special communication

FDA's misplaced priorities: premarket review under the Family Smoking Prevention and Tobacco Control Act

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ABSTRACT
Among other key objectives, the 2009 Family Smoking Prevention and Tobacco Control Act was designed to end an era of constant product manipulation by the tobacco industry that had led to more addictive and attractive products. The law requires new tobacco products to undergo premarket review by the US Food and Drug Administration (FDA) before they can be sold. To assess FDA's implementation of its premarket review authorities, we reviewed FDA actions on new product applications, publicly available data on industry applications to market new products, and related FDA guidance documents and public statements. We conclude that FDA has not implemented the premarket review process in a manner that prioritises the protection of public health. In particular, FDA has (1) prioritised the review of premarket applications that allow for the introduction of new tobacco products over the review of potentially non-compliant products that are already on the market; (2) misallocated resources by accommodating the industry's repeated submissions of deficient premarket applications and (3) weakened the premarket review process by allowing the tobacco industry to market new and modified products that have not completed the required review process.

In 2009, the US Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), providing the US Food and Drug Administration (FDA) with the authority to regulate tobacco products. As part of that authority, Congress provided that no new regulated tobacco products could enter the market without first undergoing review by FDA. In a compromise negotiated with the tobacco industry, the law 'grandfathers' tobacco products that were already on the market.[1] Products that were commercially available at the time the law was introduced, *and have not been changed in any meaningful way*, do not require FDA authorisation to stay on the market. However, the law mandates that a manufacturer submit to FDA review before any new product, including new versions of previously available products, can be sold at retail.[2] One aim of the requirement is to address the tobacco industry's history of manipulating its products to maximise addictiveness and increase attractiveness to consumers, and to prevent more harmful products from ever entering the market.[3–5]

In the almost 7 years since the enactment of the Tobacco Control Act, FDA has failed to implement the premarket review process in a manner that maximises the protection of public health. Instead, as explained in this Special Communication, the agency has misplaced its priorities, and thereby has undermined the potential public health benefits of tobacco regulation, in three distinct ways. First, rather than prioritise the removal of non-compliant products from the marketplace, FDA has given precedence to the review of applications that allow for the introduction of new tobacco products. Second, FDA has accommodated the tobacco industry's repeated submission of deficient premarket applications, rather than dismissing such flawed applications outright or allowing only reasonable amendments. Finally, even though industry marketing activities are widely publicised, FDA has failed to prioritise the enforcement of premarket review against companies that have avoided the process entirely and introduced new or modified products to the market without authorisation. These conclusions are based on our review of FDA actions on new product applications, publicly available data on industry applications to market new products, and the agency's guidance documents and public statements.

BACKGROUND ON THE TOBACCO CONTROL ACT'S PREMARKET REVIEW PROVISIONS

The cut-off date for products that are grandfathered and do not require FDA review is 15 February 2007.[2] Any new or modified product introduced after that date must be authorised by FDA before it can be sold. This includes any entirely new brand or sub-brand of a product, as well as any modification to a legally marketed product.[3] Whether FDA will authorise a new product to be sold depends on the manufacturer's ability to demonstrate that it has satisfied the criteria for one of the regulatory pathways for new products (figure 1). Under the **Premarket Tobacco Product Application (PMTA)** pathway, the manufacturer must show that introduction of a new product would be 'appropriate for the protection of the public health', taking into account 'the risks and benefits to the population as a whole, including users and nonusers of the tobacco product'.[3] In essence, this requires the applicant to show that, on balance, allowing the sale of the new product would likely reduce tobacco-related harms. The **Substantial Equivalence (SE)** pathway provides for less rigorous review if a manufacturer can show that its product is nearly the same as a predicate grandfathered product. When this pathway is being used, FDA's task is to determine whether the product is *different* from the predicate in any way that raises 'different questions of public health'.[10] If so, the SE pathway is

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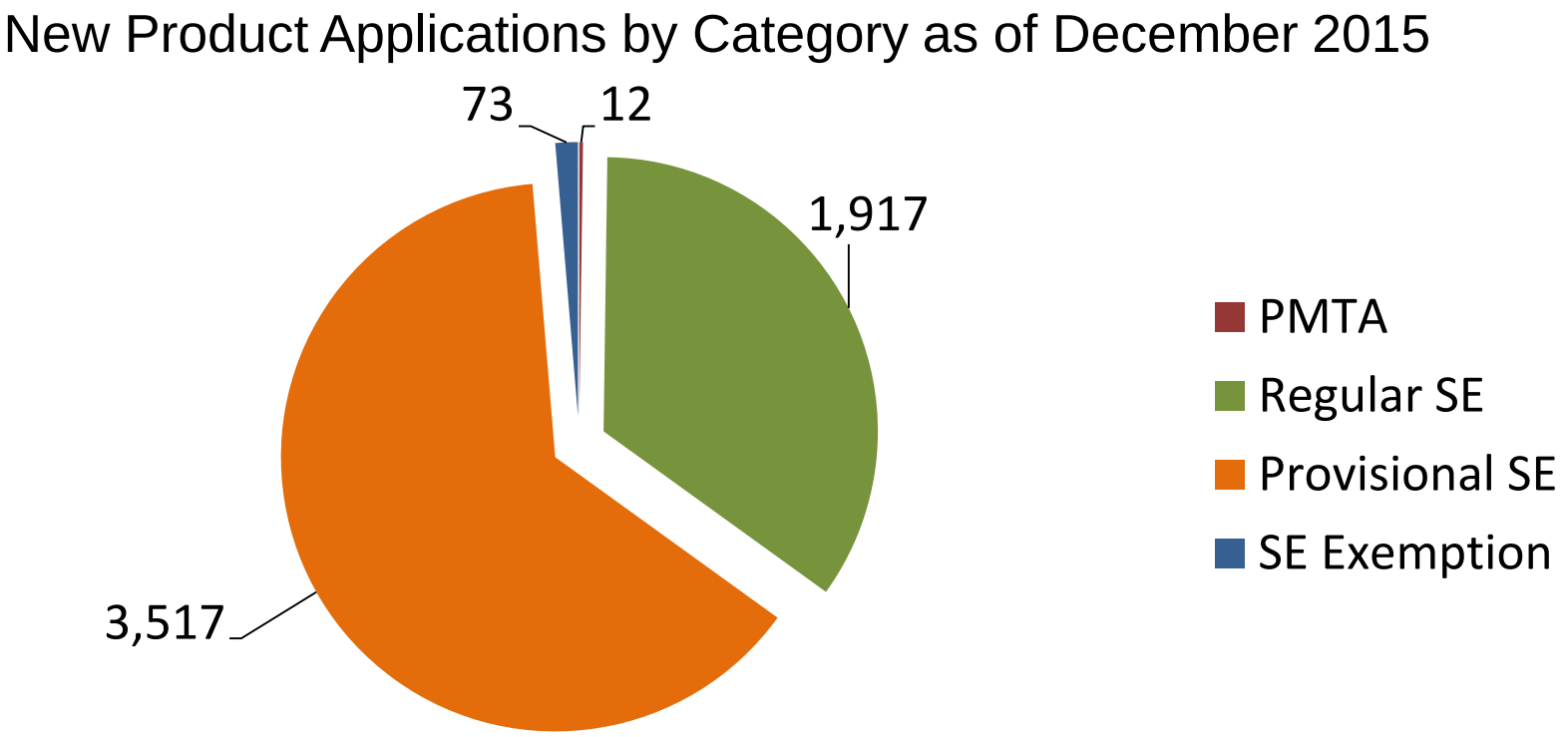
Premarket Review Under the TCA

Provisional SE	Regular SE
Allowed to be sold until removed by the FDA	Cannot be sold until authorized by the FDA

Premarket Review Under the TCA

Month	Provisional SE Reports Submitted
November 2010	10
December 2010	16
January 2011	0
February 2011	0
March 2011	3,491

Premarket Review Under the TCA



Jenson D, et al. *Tob Control* 2016; 25:246-253

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  - **FDA's Review Priority**
  - **Deficient Applications**
- Solutions to Problems

Premarket Review Under the TCA

Provisional SE	Regular SE
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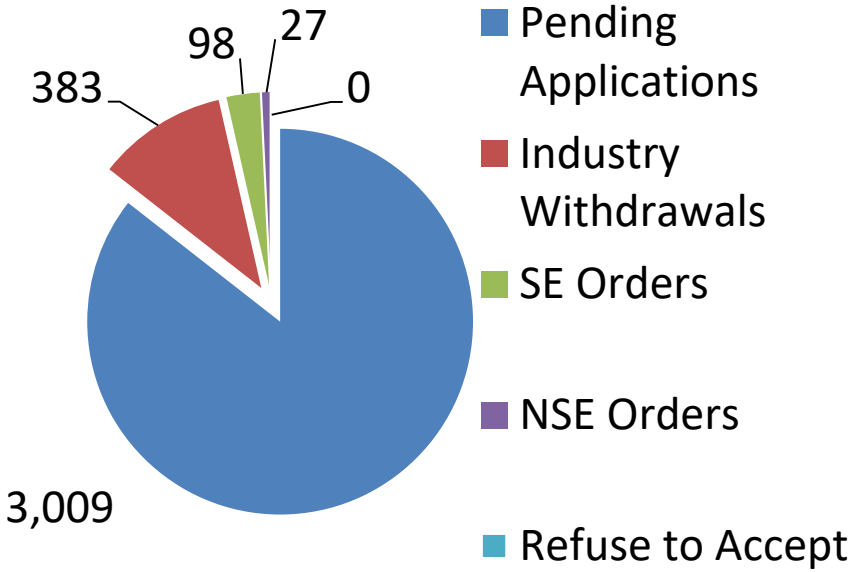
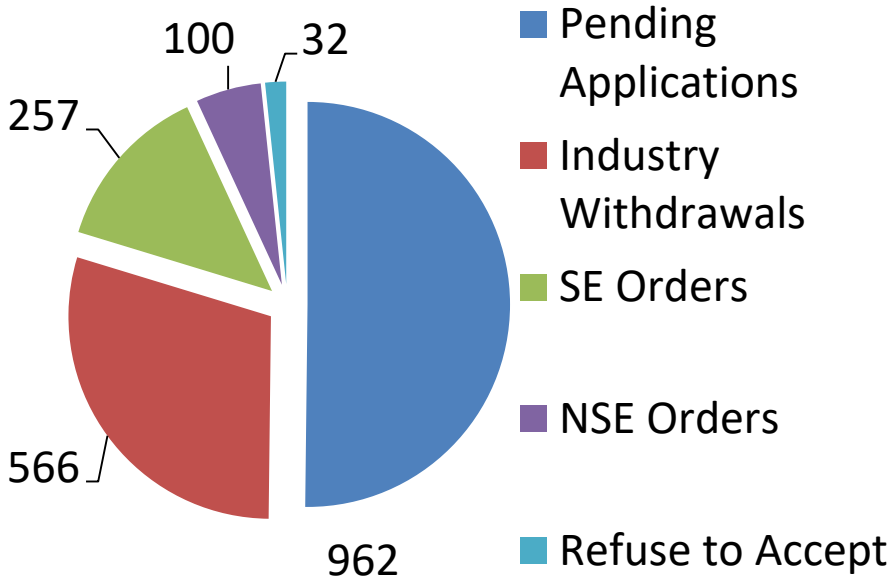
Premarket Review 2009-2016

Action on Substantial Equivalence Reports as of December 2015

Provisional SE



Regular SE



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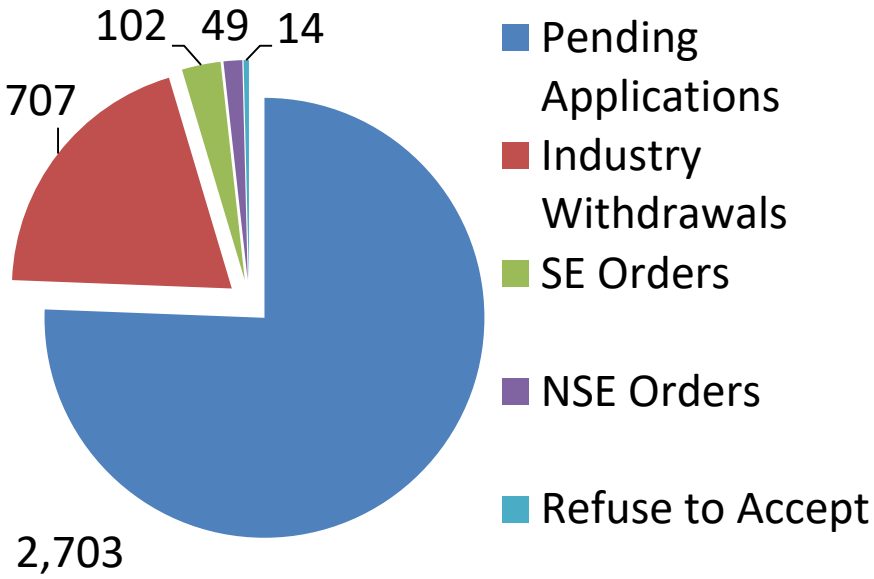
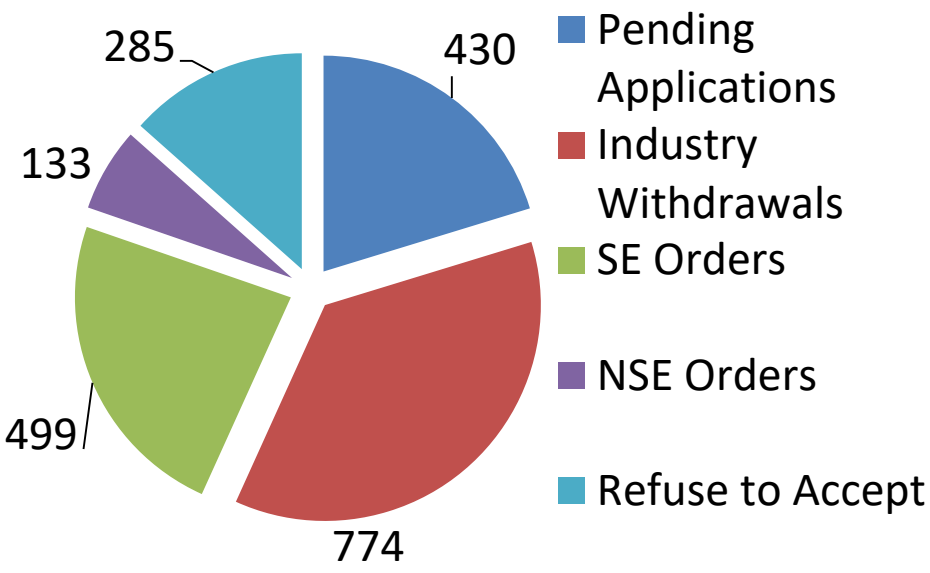
Premarket Review 2009-2016

Action on Substantial Equivalence Reports as of December 2016

Provisional SE



Regular SE



Premarket Review 2009-2016

April 24, 2012

Regular Reports (current approach)

- Has taken priority over provisional reports
  - Need an order finding new tobacco product SE to legally market product in United States
- Reviewed in first-in-first-reviewed order
- Review order has been based on the date a 905(j) is received by FDA

15

August 21, 2012

Regular Reports

SE reports that do not meet the statutory definition of provisional are "regular" reports and products covered by those reports cannot be marketed unless FDA first issues a finding of substantial equivalence. Between March 23, 2011, and July 1, 2012, FDA received 390 regular SE reports.

We are currently prioritizing the review of regular reports over provisional reports.

5

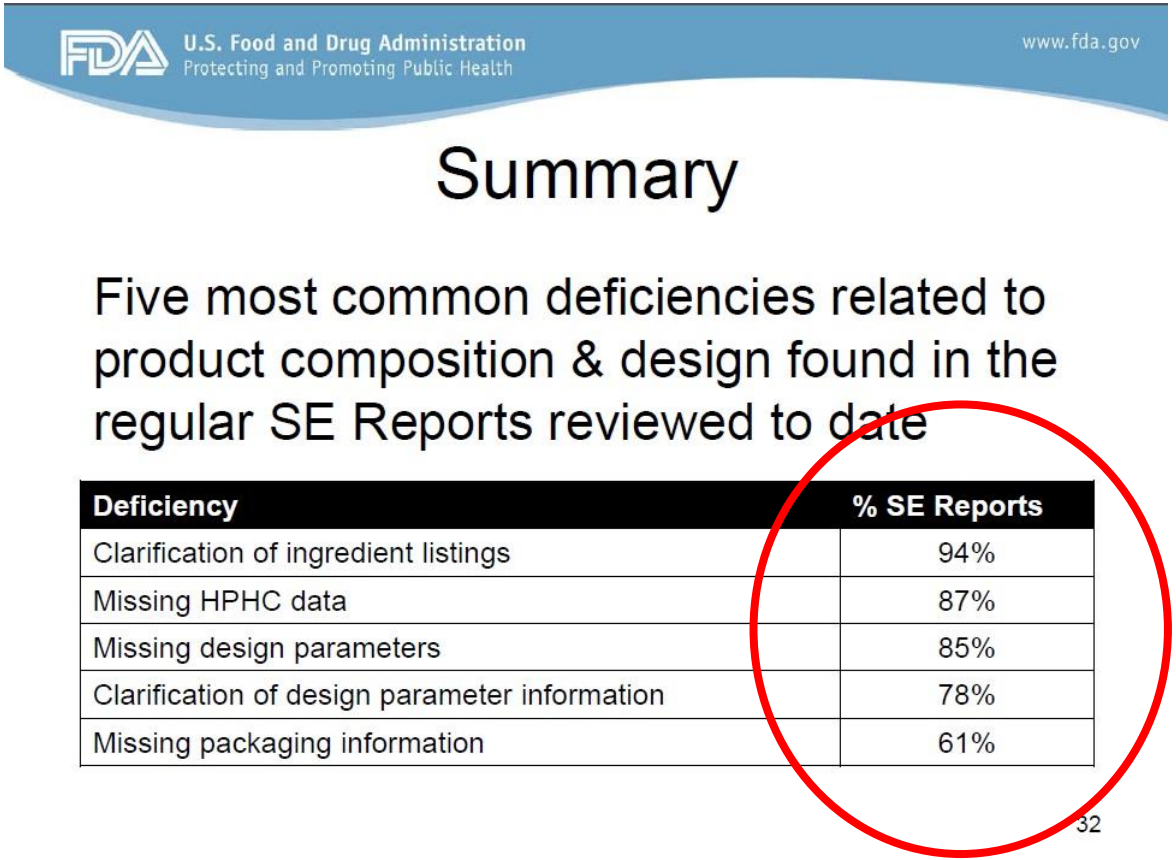
April 10, 2013

Regular SE Reports:
Prioritization for Scientific Review

- Discussed in April 24, 2012 webinar
  - Has taken priority over provisional reports
    - Need an order finding new tobacco product SE to legally market product in United States
- Reviewed in first-in-first-reviewed order

10

Premarket Review 2009-2016



Premarket Review 2009-2016

1. Your SE Report lacks information to fully identify the new tobacco product. *All* of the following is needed to fully identify the product:

    a. Product name (brand and subbrand)
    b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)
    c. Subcategory (e.g., moist snuff, filtered conventional cigarette, bidi)
    d. Package type (e.g., soft pack, hard pack)
    e. Package size (mass or, if portioned, count)
    f. Portion size, if applicable (mass)

2. Your SE Report lacks information to fully identify the predicate tobacco product. *All* of the following is needed to fully identify the product:

    a. Product name (brand and subbrand)
    b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)
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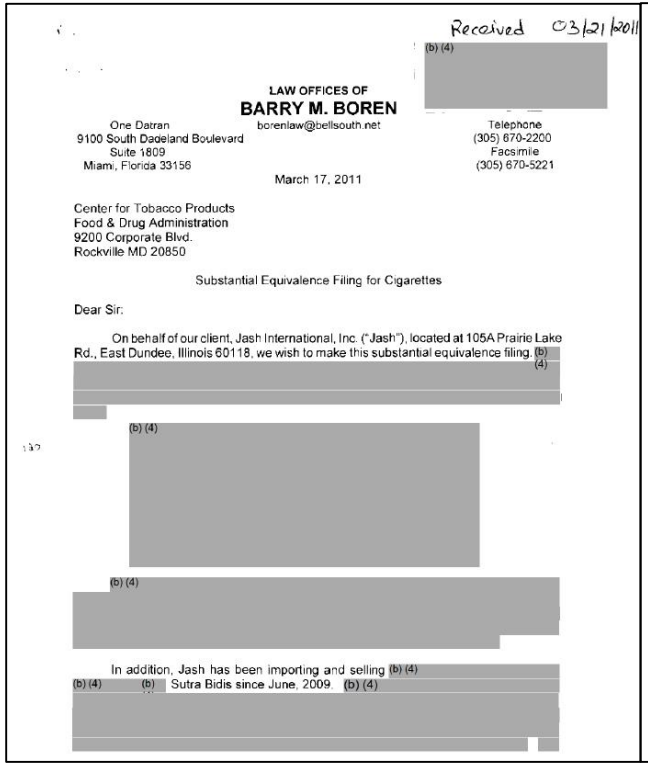
Premarket Review 2009-2016



Received 03/21/2011

(b) (4)

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March 17, 2011

Center for Tobacco Products
Food & Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Substantial Equivalence Filing for Cigarettes

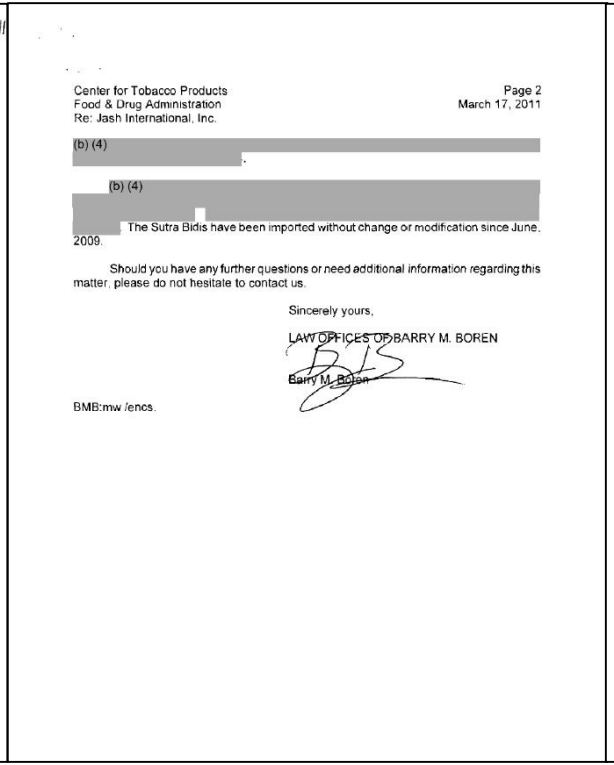
Dear Sir:

On behalf of our client, Jash International, Inc. ("Jash"), located at 105A Prairie Lake Rd., East Dundee, Illinois 60118, we wish to make this substantial equivalence filing. (b) (4)

(b) (4)

(b) (4)

In addition, Jash has been importing and selling (b) (4) (b) (4) (b) Sutra Bidis since June, 2009. (b) (4)



Center for Tobacco Products
Food & Drug Administration
Re: Jash International, Inc.

Page 2
March 17, 2011

(b) (4)

(b) (4)

The Sutra Bidis have been imported without change or modification since June, 2009.

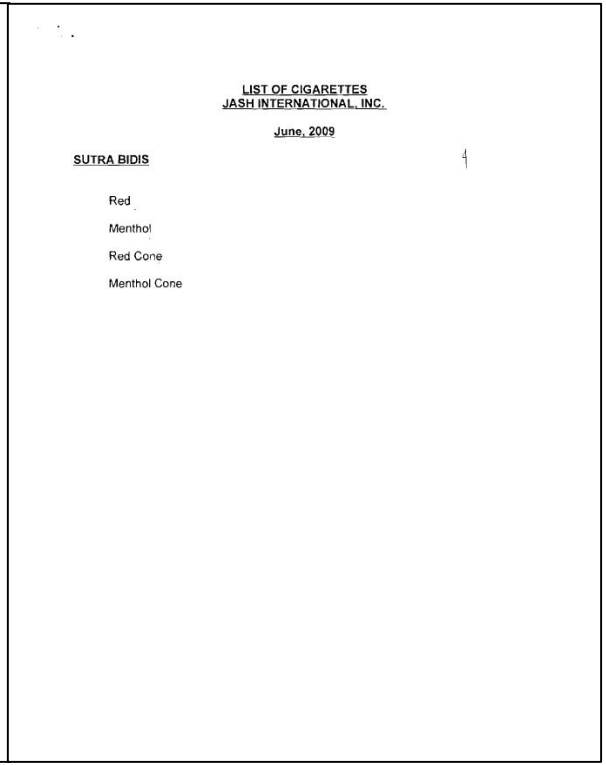
Should you have any further questions or need additional information regarding this matter, please do not hesitate to contact us.

Sincerely yours,

LAW OFFICES OF BARRY M. BOREN

Barry M. Boren

BMB:mw /encs.



LIST OF CIGARETTES
JASH INTERNATIONAL, INC.

June, 2009

SUTRA BIDIS

Red

Menthol

Red Cone

Menthol Cone

Premarket Review 2009-2016

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted 4 SE Reports listed in Table 2 of this memorandum on March 21, 2011. FDA sent the applicant administrative advice and information request letters (A/I letters) for these SE Reports on March 19, 2013. The applicant did not respond to the administrative A/I letter. However, a series of teleconferences occurred between FDA and the authorized agent to try to clarify the information in the reports and to receive necessary information for FDA to carry out review. FDA contacted the authorized agent, Mr. Barry Boren, on March 15, 2013, March 19, 2013, and April 3, 2013. These teleconferences were to determine the new tobacco products that Mr. Boren had submitted for review, the predicate tobacco products for comparison, and the first date of commercial marketing in the United States for the new tobacco products subject of the provisional SE Reports. Mr. Boren clarified that he did not have an exact date for commercial marketing for the four Sutra products; however, they were imported and sold in the United States as of June 2009. In addition, on April 12, 2013, Mr. Boren contacted FDA and stated he had sent a letter back to his client in India with FDA's information requests; however, he has not yet heard back from his client with the requested information. As some of the requested information is unique identification of the new and predicate tobacco products, FDA was unable to begin the determination of grandfathered status or scientific review. Therefore, in July 2013, FDA sent a preliminary finding letter to the applicant. FDA called Mr. Boren on August 5, 2013, to confirm receipt of the preliminary finding letter, and on August 23, 2013 to remind him of the due date for additional information requested in the preliminary finding letter. Mr. Boren stated that Jash considered (b) (4) during the August 5, 2013 phone call, but at the time of the August 23, 2013, follow up call, he stated they would not respond. The due date for the requested information in the preliminary finding letter was August 24, 2013, and the applicant has not responded.

Premarket Review 2009-2016

Manufacturer	Number of Contacts Initiated by FDA	Days on Market with Known Deficiency	Date of First Contact	Date of NSE Order	Nature of Deficiency
Star Scientific, Inc.	4	665	11/01/2012	06/28/2014	No side-by-side quantitative comparison of "other features"
Eagle River Importers, Inc.	5	744	05/06/2013	05/20/2015	New and predicate products not uniquely identified
R.J. Reynolds Tobacco Company	7	900	03/29/2013	09/15/2015	Deficient predicate product information
Jash International, Inc.	8	339	03/19/2013	02/21/2014	New and predicate products not uniquely identified
Pacific Standard Manufacturing Corporation	10	1024	11/14/2012	09/04/2015	New and predicate products not uniquely identified
LIT Distributor, Inc.	12	923	04/04/2013	10/14/2015	New and predicate products not uniquely identified
California Clinical Supply Company	16	959	12/20/2012	08/06/2015	New and predicate products not uniquely identified

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Solutions to Problems

Action on Substantial Equivalence Reports as of December 2016

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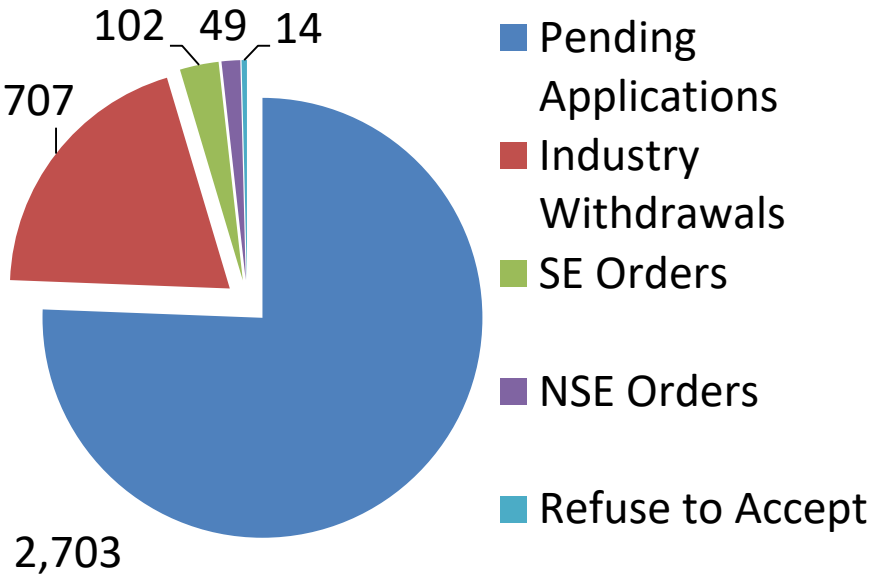
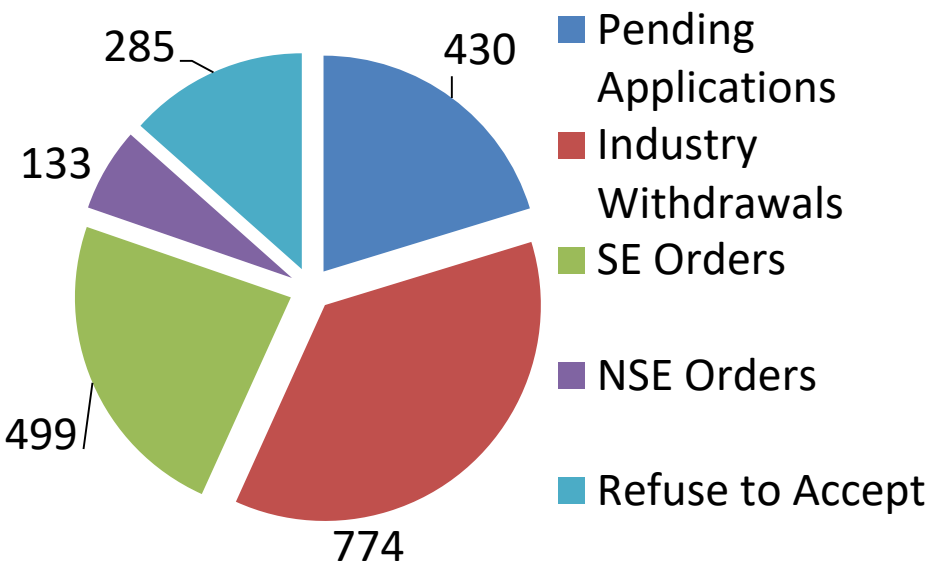


Regular SE



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