

**BEFORE THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**In the Matter of Food Labeling:  
Trans Fatty Acids in Nutrition Labeling;  
Consumer Research to Consider Nutrient Content  
and Health Claims and Possible Footnote  
or Disclosure Statements**

**Docket No. 03N-0076**

**Comments of the Staff of  
the Bureau of Economics,  
the Bureau of Consumer Protection,  
and the Office of Policy Planning**

**of the Federal Trade Commission**

**October 9, 2003\***

## I. INTRODUCTION

Consumption of *trans* fatty acids (or “*trans* fats”) increases serum cholesterol levels, thereby increasing the risk of cardiovascular disease. To provide consumers with more information about the amount of *trans* fats in foods, on July 11, 2003, the Food and Drug Administration (FDA) issued a final rule mandating that *trans* fats be listed as a separate line

deceptive or unfair acts or practices in or affecting commerce.<sup>6</sup> The FTC considers the prevention of deceptive health-related advertising claims to be one of its highest priorities and

information about diet and health are likely to lead to better informed consumers, more competition on the health attributes of food, and the formulation of healthier products.

The FTC staff has followed the regulatory developments relative to trans fats and has

submitted comments to the FDA on two previous occasions.<sup>9</sup> To assist the FDA, we provide

The FDA, however, concluded that it was premature to require the listing of *trans* fat information on the Nutrition Facts panel, because of a lack of consensus on the dietary implications of *trans* fat intake.<sup>11</sup>

In 1999, the FDA reviewed additional scientific evidence and concluded that it “consistently indicate[d] that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL-C [low density lipoprotein cholesterol] compared with consumption of diets containing cis-monounsaturated or cis-

<sup>11</sup> 64 Fed. Reg. 22,222 (1999). The FDA then announced that mandatory disclosure of

nonmisleading *trans* fat information on food labels: (2) recommended that *trans* fats not be

(4) recommended consideration of a “Reduced *Trans* Fat” claim; and (5) recommended that the FDA consider allowing health claims to inform consumers of the relationship between *trans* fats and heart disease risks.

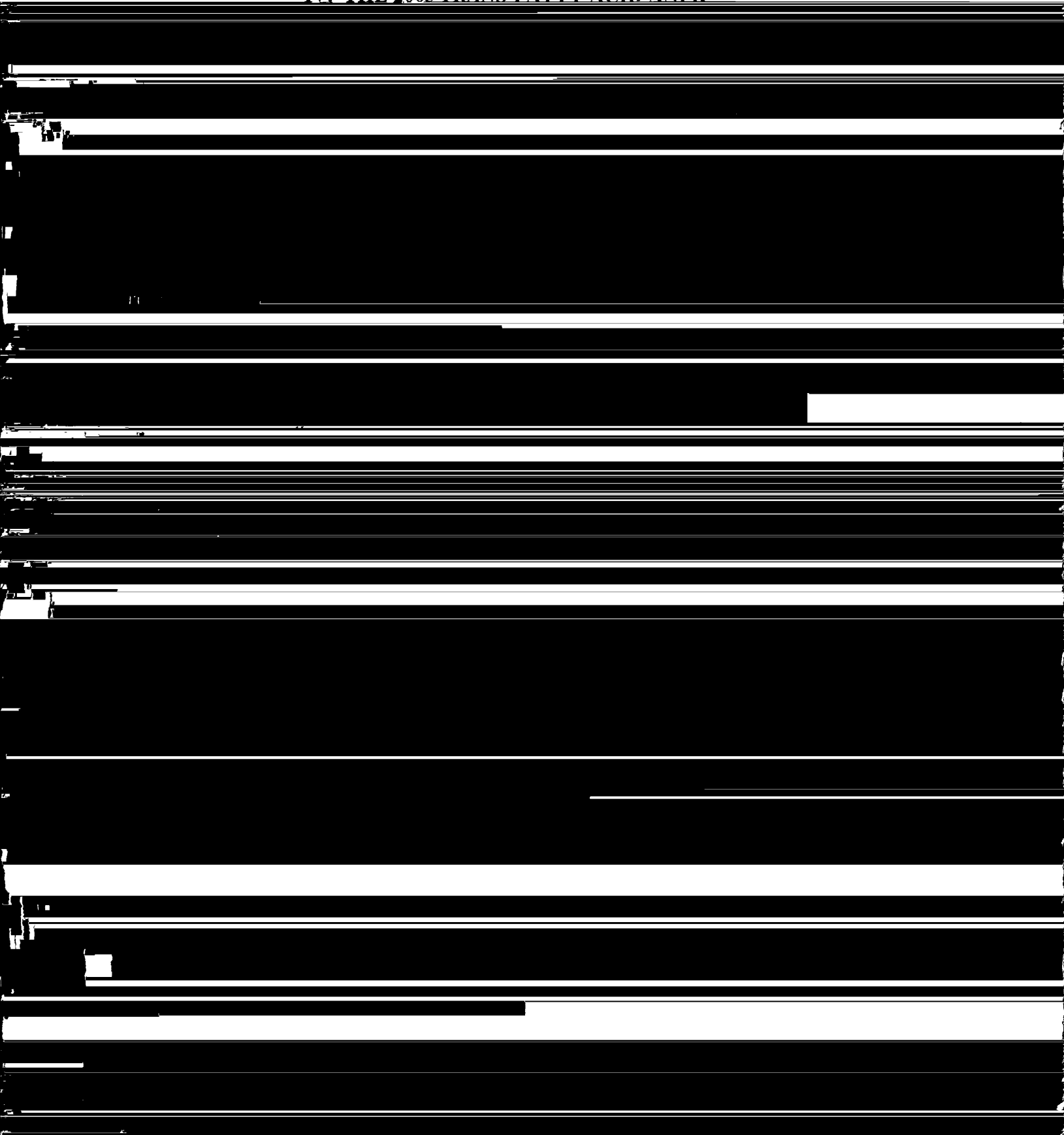
In November 2002, the FDA reopened the comment period (2002 FDA proposal).<sup>16</sup>

final rule, given the significant effect of *trans* fats on heart disease risks; and (4) reemphasized that the FDA should consider allowing truthful and nonmisleading nutrient content and health claims related to *trans* fats.

The 2002 FTC Staff Comments are available at <http://www.ftc.gov/ftc/2002/03/020301transfat.htm>.

the amount of *trans* fat in a food will make it easier for consumers to identify the foods that best meet their dietary goals.

#### **IV. THE 2003 *TRANS* FATTY ACID ANPR**





that any claim or footnote statement about *trans* fat, alone or in combination with other

innovation in such foods. Similarly, a “*trans* fat free” descriptor would help consumers

food advertising and labeling can play a vital role in fostering well informed consumers and

enforcement discretion.”<sup>27</sup>

We understand that the FDA has decided to use its discretion to allow marketers flexibility to make truthful, nonmisleading health claims relating to *trans* fats. We think that

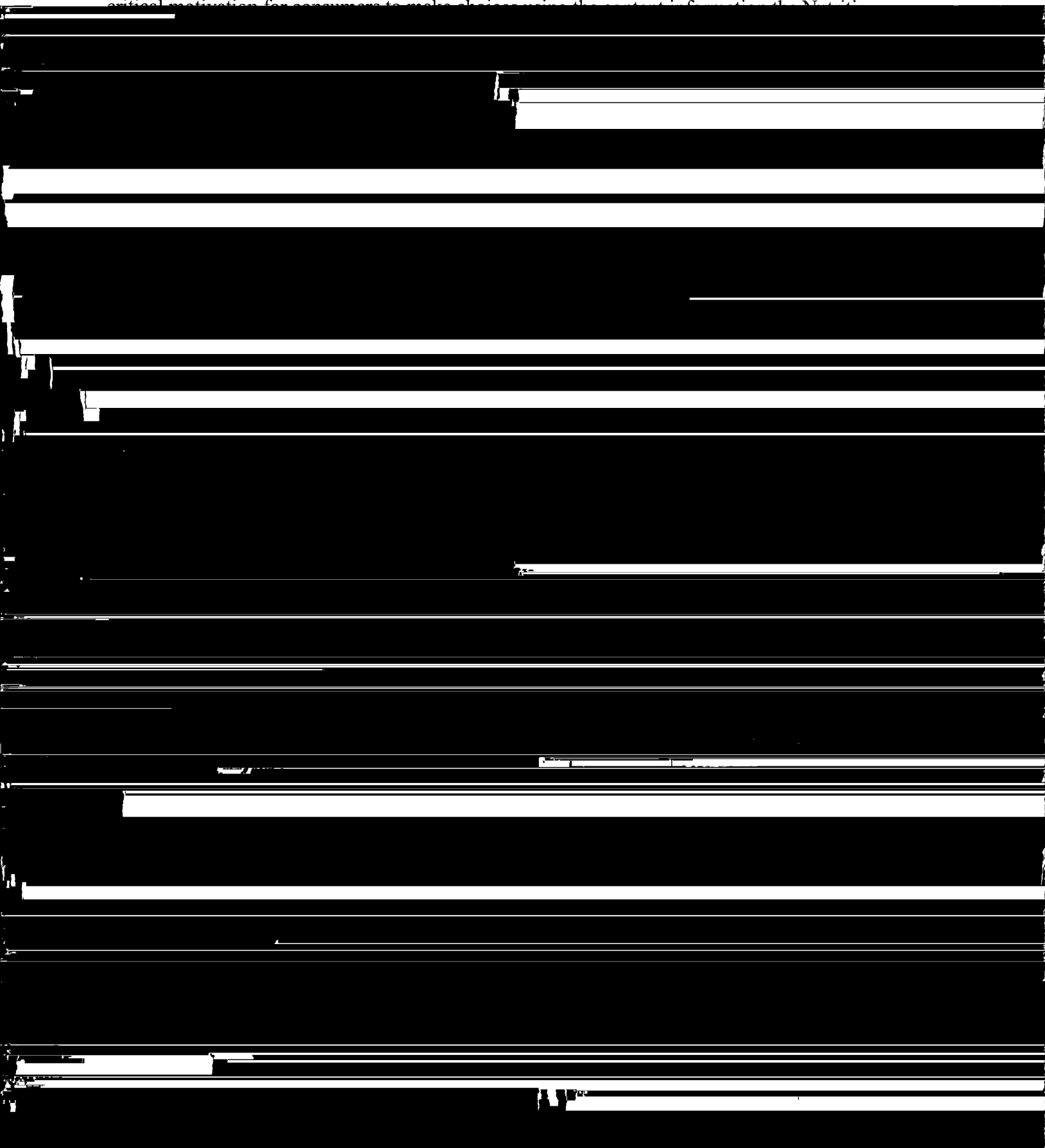
excess consumption benefits could be realized if the FDA... 11

to authorize health claims related to *trans* fats.<sup>31</sup>

consumers' knowledge could be further enhanced by authorizing food marketers to explain on

Food labels... *(The following text is heavily redacted with black bars.)*

critical motivation for consumers to make choices using the product in question. (N. 11)



the asserted governmental interest is substantial.”<sup>41</sup> If the government interest is substantial, the court “must determine whether the regulation directly advances the governmental interest asserted.”<sup>42</sup> Next, the court must determine “whether [the regulation] is not more extensive



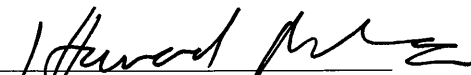
showing disclosure would not suffice to cure misleadingness.”<sup>47</sup>

consider the exercise of prosecutorial discretion in allowing truthful, nonmisleading health

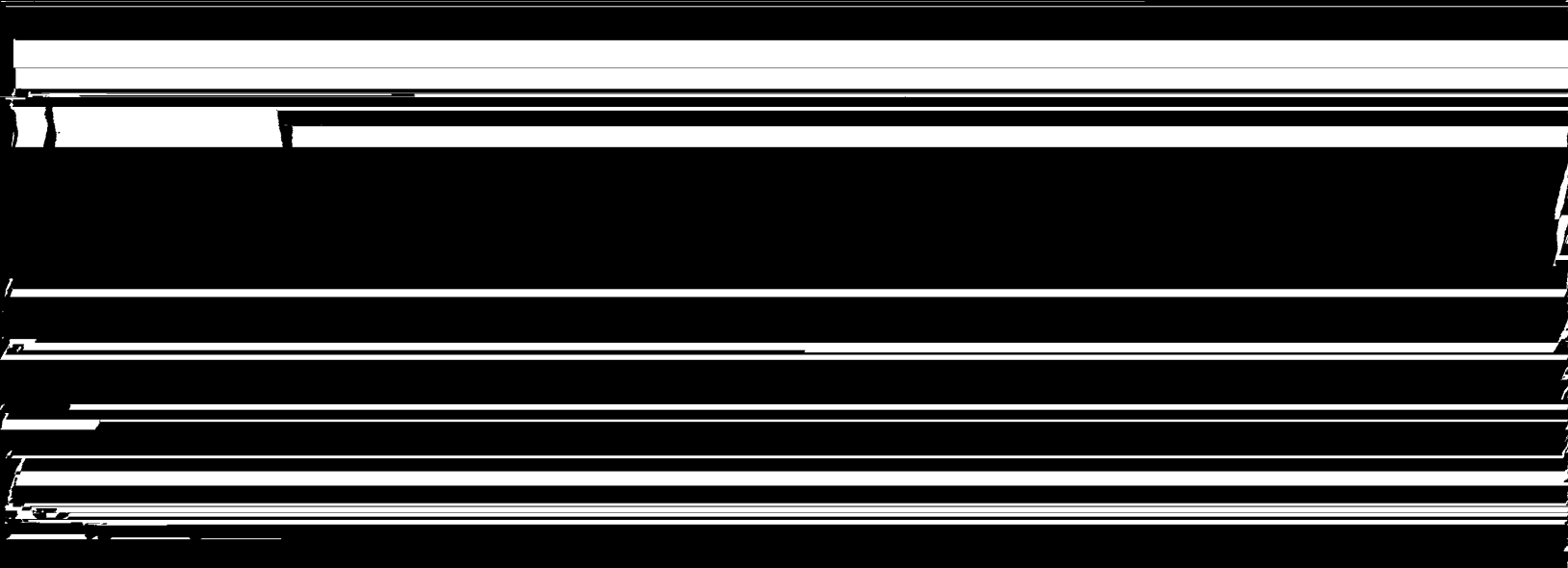
would benefit if the FDA were to go further and authorize truthful, nonmisleading nutrient content and health claims related to *trans* fats, which may be necessary given the FDA's

history of declining to permit appropriate food labels.

Respectfully submitted,



J. Howard Beales III, Director  
Thomas B. Pahl, Assistant Director,  
Division of Advertising Practices  
L. Mark Eichorn, Attorney  
Bureau of Consumer Protection



Luke M. Froeb, Director  
Pauline M. Ippolito, Associate Director  
Janis K. Pappalardo, Economist  
Bureau of Economics

