

**Public Announcement No. 2019-23 by the Ministry of Food and Drug Safety**

**Standard for Reviewing Food Labeling or Advertising and  
Filing Objections**

**March 22, 2019**

**Ministry of Food and Drug Safety (“MFDS”)**

**Standard for Reviewing Food Labeling or Advertising and Filing Objections to  
Review Results**

**Article 1 (Purpose)** This Announcement aims to prescribe matters associated with (1) reviewing procedures among others when the *Minister of Food and Drug Safety* performs a review on labeling or advertising of foods as in the proviso under Articles 10.1 and 10.4 of the *Act on Labeling and Advertising of Foods (the “Act”)* and Articles 4.1 through 4.3 and 6.1 through 6.3 of the Enforcement Decree of the same Act and (2) objections, including the method and procedure of filing an objection against a review result.

**Article 2 (Requesting a Review)** ① A person who seeks a review of the labeling or advertising (the “Requester”) as in the proviso under Article 10.1 of the Act, shall submit a form named the *Request for Review on Labeling/Advertising of Foods* as provided in Attached Sheet #1 together with the following documents to the Minister of Food and Drug Safety:

1. Contents of labeling or advertising;
2. A copy of the Item Manufacturing Report, Item Manufacturing Declaration, or Certificate of Import Declaration, if applicable;
3. Product Manual; and,
4. Reference materials such as research papers on the product, which may help with the review, if necessary.

② The Minister of Food and Drug Safety may order supplementation or return the request for review if reviewing is impossible because of the omission of any document under Paragraph 1 or the lack of contents in the documents submitted. In this case, the method and procedures associated with the ordering of supplementation or returning of the request shall be governed by the Civil Petitions Treatment Act.

**Article 3 (Reviewing and Results Processing)** ① The Minister of Food and Drug Safety shall review the labeling or advertising as requested under Paragraph 2 (including Changes; the same shall apply to the rest of this Article.) pursuant to the reviewing standards under Article 4.1 of the Enforcement Decree of the Act (the “Enforcement Decree”).

② The Minister of Food and Drug Safety shall notify the Requester of the results of the review under Paragraph 1 pursuant to Article 4.2 of the Enforcement Decree. In this case, the same notification shall be provided to the competent authorities having jurisdiction over the Requester’s business location, which deal with business licenses and reporting or registration.

③ If a person whose labeling or advertising has been reviewed under Paragraph 1 wishes to change the contents reviewed, he/she shall submit to the Minister of Food and Drug Safety the form named the *Request for Change to Reviewed Food Labeling or Advertising* as provided in Attached Sheet #2 attaching the following documents. In this case, the processing of the submitted form and documents shall be subject to Article 2.2 hereof:

1. A copy of the reviewed labeling or advertising;
2. A copy of the changed labeling or advertising; and
3. Other references necessary for the review.

④ Notwithstanding Paragraph 3, if the change involves deletion or modification (the “Minor Changes”) of some of the contents to the extent that they do not make any changes to the content reviewed under Paragraph 1, a request for Review of Changes may not be required. In this case, the person intending to make Minor Changes to the content that has been reviewed shall notify the Minister of Food and Drug Safety of the Minor Changes before labeling or advertising.

⑤ The Minister of Food and Drug Safety, who has been notified of the Minor Changes under the latter part of Paragraph 4, shall rereview the labeling/advertising pursuant to Paragraph 3 if the Minor Changes are recognized as different from the previous review results.

**Article 4 (Filing an Objection)** ① A person who is dissatisfied with the review results as in

the proviso under Article 10.4 of the Act may file an objection with the Minister of Food and Drug Safety using the form named the *Objection to Review Results on Labeling or Advertising* provided in Attached Sheet #3 attaching the following documents:

1. Contents of the labeling or advertising;
2. A copy of the Notice of Review Result; and
3. Other references necessary for the review.

② The Minister of Food and Drug Safety shall process the documents under Paragraph 1 pursuant to Article 2.2 hereof, and apply the reviewing standards to the objection filed under Article 4.1 of the Enforcement Decree.

③ The results of the review of the objection shall be determined either as “accepted” or “rejected.” However, the Minister of Food and Drug Safety may attach a condition that the contents of the labeling or advertising shall be modified or supplemented in part if he/she decides to accept the objection. If an acceptance decision is made for an objection, it shall be deemed that the labeling or advertising has been duly reviewed pursuant to Article 10.1 of the Act.

④ The Minister of Food and Drug Safety shall notify the Requester of the review result of the objection under Paragraph 1 pursuant to Article 6.2 of the Enforcement Decree.

**Article 5 (Advice)** The Minister of Food and Drug Safety may seek opinions or advice from the Committee under Article 12 of the Act on matters related to the review or contents of the objection.

**Article 6 (Review Period)** Pursuant to *the Regulation on the Issue and Management of Directives and Established Rules*, this Standard shall be reviewed for its reasonableness to take necessary measures, such as making improvement thereto, once every third anniversary (by June 30) starting from July 1, 2019.

**Article 1 (Enforcement Date)** This Notification shall enter into force on the date of its announcement.

**Article 2 (Abolishment of Other Notifications)** The following Notifications shall be abolished:

1. *The Standard for Reviewing Labeling or Advertising of Foods for Special Dietary Uses* (MFDS Notification)
2. *The Standard for Reviewing Labeling or Advertising of Health Functional Foods* (MFDS Notification)

<b>Request for Review on Labeling/Advertising of Foods</b>						Processing Time
						20 days
Requester	Name		Date of Birth			
	Address	(Telephone ) (Fax )				
Business	Company/Trade Name		Location			
	Business Type		Business License (Reg. Report) No.			
Product to Be Reviewed	Product Name					
Contents to Be Reviewed	Labeling					
	Advertisement	Advertising Medium		Advertising Company		
		Content of Advertising to Be Reviewed: (to be attached hereto)				
<p>I hereby request for a review of the labeling/advertising of the abovementioned product under Article 2 of the Standard for Reviewing Food Labeling or Advertising and Filing Objections to Review Results.</p> <p style="text-align: right;">Year____ Month____ Day____</p> <p style="text-align: center;">Requester: (Signature or Seal)</p> <p><b>To the Minister of Food and Drug Safety</b></p>						
※ Required Documents: 1. A copy of the content of labeling or advertising; 2. A copy of the Item Manufacturing Report, Item Manufacturing Declaration, or Certificate of Import Declaration, if applicable; 3. A Product Manual containing the following information: A. For foods other than health functional foods - Product name, ingredients mixing ratio, food type, description of the manufacturing method, packaging methods and units B. For health functional foods - Product name, ingredients mixing ratio, formulation and manufacturing methods, the amount and method of intake, cautions for intake, packaging methods and units 4. Reference materials that may be helpful to the review, if necessary.						Processing Fee          KRW 100,000

<b>Request for Change to Reviewed Food Labeling or Advertising</b>				Processing Time
				20 days
Requester	Name		Date of Birth	
	Address	(Telephone ) (Fax )		
Business	Company/Trade Name		Location	
	Business Type		Business License (Reg. Report) No.	
Product to Be Reviewed	Product Name			
Changes	Before Change	After Change	Reason for Change	
<p>I hereby request for a change to the reviewed labeling/advertising of the abovementioned product under Article 3.3 of the Standard for Reviewing Food Labeling or Advertising and Filing Objections to Review Results.</p> <p style="text-align: right;">Year____ Month____ Day____</p> <p style="text-align: center;">Requester: (Signature or Seal)</p> <p><b>To the Minister of Food and Drug Safety</b></p>				
※ Required Documents 1. A copy of the reviewed labeling or advertising; 2. A copy of the changed labeling or advertising; and 3. Other references for the review, if necessary.				Processing Fee
				KRW 100,000

<b>Objection to Review Results on Labeling or Advertising</b>				Processing Time
				30 days
Applicant	Name		Date of Birth	
	Address	(Telephone ) (Fax )		
Business	Company/Trade Name		Location	
	Business Type		Business License (Reg. Report) No.	
Product to Be Reviewed	Product Name			
Advertising Medium				
Purport and Reasons for Objection				
<p>I hereby file an objection as above to the review results on the abovementioned product under Article 4.1 of the Standard for Reviewing Food Labeling or Advertising and Filing Objections to Review Results.</p> <p style="text-align: right;">Year____ Month____ Day____</p> <p style="text-align: right;">Requester: (Signature or Seal)</p> <p><b>To the Minister of Food and Drug Safety</b></p>				
<p>※ Required Documents</p> <ol style="list-style-type: none"> <li>1. Contents of the labeling or advertising;</li> <li>2. A copy of the Notice of Review Result; and</li> <li>3. Other references for the review, if necessary.</li> </ol>				