UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Crabmeat; Amendment of Common or Usual Name Regulation

FINAL REGULATORY IMPACT ANALYSIS

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Executive Summary

In a final rule published on July 3, 1995, the Food and Drug Administration (FDA) amended the common or usual name regulation for crabmeat by adding "Brown King crabmeat" as the sole common or usual name for the species *Lithodes aequispina*. In response to the 2017 Consolidated Appropriations Act, FDA is amending the common or usual name regulation for the species *Lithodes aequispina*[1] from "Brown King crabmeat" to "Golden King crabmeat." The estimated present value of the costs of this final rule range from $1.5 million to $7.5 million, with a mean estimate of $3.4 million (2016$), while the estimated present value of the benefits of this final rule are zero. The estimated present value of the net benefits of this final rule range from -$7.5 million to -$1.5 million, with a mean estimate of -$3.4 million (2016$). The estimated annualized costs of this final rule range from $0.1 million to $0.5 million, with a mean estimate of $0.2 million, using a 3 percent discount rate, and from $0.1 million to $0.7 million, with a mean estimate of $0.3 million, using a 7 percent discount rate (2016$). Estimated annualized benefits of this final rule are zero. The estimated annualized net benefits of this final rule range from -$0.5 million to -$0.1 million, with a mean estimate of -$0.2 million, using a 3 percent discount rate, and from -$0.7 million to -$0.1 million, with a mean estimate of -$0.3 million, using a 7 percent discount rate (2016$). Finally, there are no cost savings associated with this final rule.

1 The Consolidated Appropriations Act, 2017, uses "*Lithodes aequispinus*" rather than "*Lithodes aequispina.*"

I. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866 and is not a deregulatory action for purposes of Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that the mean cost per crab covered by the final rule is $0.23 (2016$) (refer to Section F for details). We estimate that the revenue per crab covered by the final rule ranges from $17.65 to $99.42 (2016$) (Ref. 1, Alaska Department of Fish and Game; Ref. 2, Captain Jack's Seafood Locker; Ref. 3, 10th and M Seafoods; Ref. 4, Great-Alaska-Seafood; Ref. 5, Island Seafoods). Because the cost per crab covered by the final rule as a percentage of the revenue per crab covered by the final rule is small, ranging from 0.2 percent to1.3 percent, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of the Final Rule

In a final rule published on July 3, 1995, FDA amended the common or usual name regulation for crabmeat by adding "Brown King crabmeat" as the sole common or usual name for the species *Lithodes aequispina*. In response to the 2017 Consolidated Appropriations Act, FDA is amending the common or usual name regulation for crabmeat derived from the species *Lithodes aequispinus* from "Brown King crabmeat" to "Golden King crabmeat."

C. Summary of Costs and Benefits and Cost Savings of the Final Rule

1. Summary of Costs and Benefits of the Final Rule

The cost of this rule is the relabeling costs incurred by manufacturers, wholesalers, and retailers of *Lithodes aequispinus* associated with changing the trade name from "Brown King Crab" to "Golden King Crab" on product packaging. We estimate that there will be a relabeling cost at each of the manufacturer, wholesaler, and retailer levels associated with each of the estimated 4,873,215 *Lithodes aequispinus* in this year's United States (U.S.) marketplace. Using the FDA Labeling Cost Model, we estimate that the present value of the total cost of these labeling changes is $3.4 million at the mean (2016$). This is illustrated below in Table 1.

A typical source of benefits for common or usual name rules is reduced consumer confusion associated with ascribing a single, common name to the product that is the subject of the rule. However, this is not the first time that a single, common name is being assigned to the crab species *Lithodes aequispinus*. The possibility that there might be *increased* consumer confusion related to the common or usual name change from "Brown King crabmeat" to "Golden King crabmeat" is unlikely given consumer familiarity with both names. Another potential source of benefits of this final rule is that changing the common or usual name from "Brown King crabmeat" to "Golden King crabmeat" might produce a small increase in the demand for the crab species *Lithodes aequispinus*, as consumers might view "Golden King crabmeat" as a more palatable name than "Brown King crabmeat." However, given consumer familiarity with both names, this is unlikely. Hence, we estimate that there are zero benefits associated with this final rule. This is shown below in Table 1.

The present value of the net benefits of this final rule is -$3.4 million at the mean (2016$). This is presented below in Table 1.

Table 1 – Summary of the Costs and Benefits of the Final Rule (in millions of 2016$)

	Low			Mean			High		
Present Value	**Benefits**	**Costs**	**Net Benefits**	**Benefits**	**Costs**	**Net Benefits**	**Benefits**	**Costs**	**Net Benefits**
3%	$0	$1.5	-$1.5	$0	$3.4	-$3.4	$0	$7.5	-$7.5
7%	$0	$1.5	-$1.5	$0	$3.4	-$3.4	$0	$7.5	-$7.5
Annualized									
3%	$0	$0.1	-$0.1	$0	$0.2	-$0.2	$0	$0.5	-$0.5
7%	$0	$0.1	-$0.1	$0	$0.3	-$0.3	$0	$0.7	-$0.7

Notes: There are no cost savings associated with this final rule. The present value of costs using a 3 percent discount rate equals the present value of costs using a 7 percent discount rate because costs, which are comprised solely of labeling costs, are one time and up front. Annualized amounts are estimated using Microsoft Excel's PMT function and a 20 year annualization period.

2. Summary of Cost Savings of the Final Rule

As illustrated below in Table 2, there are no cost savings associated with this final rule.

Table 2 – Summary of the Cost Savings of the Final Rule (in millions of 2016$ over 20 year period)

	Low			Mean			High		
Present Value	**Costs**	**Cost Savings**	**Net Costs**	**Costs**	**Cost Savings**	**Net Costs**	**Costs**	**Cost Savings**	**Net Costs**
3%	$1.5	$0	$1.5	$3.4	$0	$3.4	$7.5	$0	$7.5
7%	$1.5	$0	$1.5	$3.4	$0	$3.4	$7.5	$0	$7.5

Annualized									
3%	$0.1	$0	$0.1	$0.2	$0	$0.2	$0.5	$0	$0.5
7%	$0.1	$0	$0.1	$0.3	$0	$0.3	$0.7	$0	$0.7

Notes: The present value of costs using a 3 percent discount rate equals the present value of costs using a 7 percent discount rate because costs, which are comprised solely of labeling costs, are one time and up front. Annualized amounts are estimated using Microsoft Excel's PMT function and a 20 year annualization period.

D. Market Failure Requiring Federal Regulatory Action

There is no discernible market failure resulting from "Brown King crabmeat" as the current common or usual name for the species *Lithodes aequispinus*. The only potential source of market failure that we are able to identify is that the name "Brown King crabmeat", because it is an arguably less apt and palatable descriptor of the species than "Golden King crabmeat," artificially suppresses demand for the species. However, consumers are familiar with both names, as both are currently used in the marketplace (Ref. 6, Vinik; Ref. 7, Wingfield and McDonald; Ref. 2, Captain Jack's Seafood Locker). Hence, this is an unlikely source of market failure.

E. Coverage of the Rule and Industry Overview

Using Dun and Bradstreet (D&B) data, we estimate that there are currently 125 manufacturers of products derived from *Lithodes aequispinus*, 7,273 wholesalers of *Lithodes aequispinus* crabmeat, and 159,534 retailers of *Lithodes aequispinus* crabmeat in the U.S., the latter figure which includes meat and fish markets as well as grocery stores.

Our estimate of the total number of *Lithodes aequispinus* in the U.S. marketplace comes from two data sources - Commercial Operator's Annual Reports (COAR) data from the Alaska Department of Fish and Game (ADF&G) and United Nations Commodity Trade Statistics data. Using these data, we estimate that 902,047 *Lithodes aequispinus* will be harvested in the U.S. and roughly 3,971,168 *Lithodes aequispinus* will be imported into the U.S. this year which, combined, yield an estimate of the total number of *Lithodes aequispinus* in this year's U.S. marketplace of 4,873,215.

As a result of this final rule, we estimate that there will be a relabeling cost at each of the manufacturer, wholesaler, and retailer levels associated with each of these 4,873,215 *Lithodes aequispinus* related to changing the name of the crab from Brown King Crab to Golden King Crab.[2]

F. Costs and Benefits of Regulatory Options – Detailed Analysis

We have identified four regulatory options for the final rule:

1) No new federal regulatory action

[2] As previously stated, both Brown King Crab and Golden King Crab are used in the marketplace. However, we do not know how many, if any, of these 4,873,215 *Lithodes aequispinus* are already labeled as Golden King Crab. Hence, we conservatively estimate that all of these 4,873,215 *Lithodes aequispinus* are currently labeled as Brown King Crab and, thus, will require a label change.

2) The final rule
3) The final rule, but with a 1 year compliance period
4) The final rule, but which also allows for "Brown King crabmeat" as the common or usual name for the species Lithodes aequispinus

1. Option 1 – No New Federal Regulatory Action

This option serves as our baseline. We define costs and benefits relative to this baseline. By definition, this baseline has no costs and no benefits.

2. Option 2 – The Final Rule

In this final rule, in response to the 2017 Consolidated Appropriations Act, FDA is amending the common or usual name regulation for the species *Lithodes aequispinus* from "Brown King crabmeat" to "Golden King crabmeat." Under this option, manufacturers, wholesalers, and retailers of crabmeat derived from *Lithodes aequispinus* will have until January 1, 2020, to relabel such crab as Golden King Crab.

i. Costs

The cost of this rule is the relabeling costs incurred by manufacturers, wholesalers, and retailers of *Lithodes aequispinus* associated with changing the trade name from "Brown King Crab" to "Golden King Crab" on product packaging. Relabeling costs are estimated using the FDA Labeling Cost Model (Ref. 8, RTI International). The model, which was built based on discussions with trade associations and product manufacturers, provides estimates of the costs of making labeling changes for a range of food products. Because of the number of steps involved in changing the information on food packaging and labeling, the entire labeling change process generally takes several months (Ref. 8, RTI International). Labeling costs, which include labor, materials, inventory (discarded inventory and disposal costs), recordkeeping, and in certain cases recurring costs associated with package size increases, are first calculated on a per-Universal Product Code (UPC) basis and then aggregated across each product category, and are calculated separately as low, mean, and high cost estimates (Ref. 8, RTI International). To determine the UPC counts in each product category, the model utilizes 2012 Nielsen ScanTrack data (Ref. 8, RTI International).

The model allows the user to select the types of products that would be covered under the regulation, the type of label change (extensive, major, or minor) that would be required under the regulation, and the compliance period (3 months to 60 months, in 3 month increments) (Ref. 8, RTI International). A minor label change is defined as a one-color-printing plate change that does not require a label redesign (Ref. 8, RTI International). Examples include one or more of the following: changes to the net quantity statement, minimal changes to the Nutrition or Supplement Facts panel, minimal changes to an ingredient list, the addition of a toll-free number, and minimal changes to a claim, caution statement, or disclaimer on the back or side of a package (affecting one color/plate) (Ref. 8, RTI International). A major label change is defined as a multiple color/printing plate change that requires a label redesign (Ref. 8, RTI International).

Examples include changes to the name of the product, changes to the acceptable market name or fanciful (trade) name for a food product, the requirement for a product to provide a Nutrition or Supplement Facts panel when none was previously required, substantial changes to an ingredient list, substantial changes to or elimination of a claim, the addition of or substantial changes to a caution statement, and the addition of or substantial changes to a disclaimer (Ref. 8, RTI International). An extensive label change is defined as a major format change that requires a change to the product packaging to accommodate labeling information (Ref. 8, RTI International). Examples include the addition of a peel-back label and increases in the package surface area for labeling information (Ref. 8, RTI International).

Available data show that most products that are voluntarily relabeled are relabeled in a 2- to 5-year cycle, with private label[3] products less likely to be relabeled in any given year than branded products (Ref. 8, RTI International). Companies that can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) will incur lower costs associated with the required labeling change than they would otherwise (Ref. 8, RTI International). Longer compliance periods increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling changes (Ref. 8, RTI International). However, even if companies can coordinate a required labeling change, the FDA Labeling Cost Model includes costs of administrative and recordkeeping activities associated with labeling changes because companies still incur costs associated with understanding the regulation, determining their response, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels (Ref. 8, RTI International). Other types of costs, though, such as prepress, graphic design, and engraving plates or cylinders, are not attributable to the regulation if the required labeling change is coordinated with a planned voluntary label change (Ref. 8, RTI International).

As described above, a change to the common or usual name or fanciful (trade) name for a food product represents a major labeling change. Hence, using the FDA Labeling Cost Model, we estimated per-sales-unit labeling costs of a major label change for the "Seafood" product category for a 4.5 month compliance period.[4] These costs, which are in 2016 dollars and range from 10 cents per sales unit to 51 cents per sales unit with a mean estimate of 23 cents per sales unit, are illustrated below in Table 3.

Table 3 – Labeling Costs Per Sales Unit (4.5 Month Compliance Period) (in 2016$)

	Low	Mean	High
Labeling Cost Per Sales Unit	$0.10	$0.23	$0.51

As previously stated, the total number of *Lithodes aequispinus* in this year's U.S. marketplace is 4,873,215. We estimate that there will be a relabeling cost at each of the manufacturer, wholesaler, and retailer levels associated with each of these 4,873,215 *Lithodes*

[3] Branded products make their way to store shelves by way of branded food manufacturers and distributors (e.g., Hunt's ketchup, French's mustard). Private label products make their way to store shelves either by way of in-house manufacturing or manufacturers who specialize in the manufacture of private label products (e.g., Wal-Mart's "Great Value" product line).

[4] The FDA Labeling Cost Model does not allow for a compliance period of 4.5 months. Thus, our estimate of per-sales-unit labeling costs equals the average of the 3 month and 6 month compliance period estimates of per-sales-unit labeling costs.

aequispinus related to changing the name of the crab from Brown King Crab to Golden King Crab. Because we do not know how many, if any, of these 4,873,215 *Lithodes aequispinus* are already labeled as Golden King Crab, we conservatively estimate that all of these 4,873,215 *Lithodes aequispinus* are currently labeled as Brown King Crab and, thus, will require a label change.

The present value of the total cost of this labeling change in 2016 dollars is summarized below in Table 4 and ranges from $1.5 million to $7.5 million, with a mean estimate of $3.4 million. Using a 20 year annualization period[5], annualized labeling costs range from $0.1 million to $0.5 million, with a mean estimate of $0.2 million, using a 3 percent discount rate, and from $0.1 million to $0.7 million, with a mean estimate of $0.3 million, using a 7 percent discount rate (2016$).

Table 4 – Total Labeling Costs (4.5 Month Compliance Period) (in 2016$)

	Low	Mean	High
Manufacturer Level	$487,322	$1,120,839	$2,485,340
Wholesaler Level	$487,322	$1,120,839	$2,485,340
Retailer Level	$487,322	$1,120,839	$2,485,340
Total Labeling Costs	**$1,461,966**	**$3,362,517**	**$7,456,020**
Annualized (3%)	$98,267	$226,014	$501,162
Annualized (7%)	$137,999	$317,398	$703,796

Notes: There are no cost savings associated with this final rule. The present value of labeling costs using a 3 percent discount rate equals the present value of labeling costs using a 7 percent discount rate because relabeling costs are one time, up front costs. We estimate annualized labeling costs using Microsoft Excel's PMT function and a 20 year annualization period.

ii. Benefits

A typical source of benefits for common or usual name rules is reduced consumer confusion associated with ascribing a single, common name to the product that is the subject of the rule. However, this is not the first time that a single, common name is being assigned to the crab species *Lithodes aequispinus*. For example, just over 20 years ago, in a July 3, 1995 final rule, the single, common name "Brown King crabmeat" was assigned to the *Lithodes aequispinus* species. That there might be *increased* consumer confusion related to the common or usual name change from "Brown King crabmeat" to "Golden King crabmeat" is unlikely given consumer familiarity with both names (both names are currently used in the marketplace (Ref. 6, Vinik; Ref. 7, Wingfield and McDonald; Ref. 2, Captain Jack's Seafood Locker)). Hence, we estimate that there are zero benefits, positive or negative, associated, respectively, with reduced or increased consumer confusion as a result of changing the common or usual name of *Lithodes aequispinus* from "Brown King crabmeat" to "Golden King crabmeat".

Another potential source of benefits of this final rule is that changing the common or usual name from "Brown King crabmeat" to "Golden King crabmeat" might produce a small increase in the demand for the crab species *Lithodes aequispinus*, as consumers might view "Golden King crabmeat" as a more palatable name than "Brown King crabmeat". However, this

[5] The common or usual name for *Lithodes aequispinus* was last changed approximately 20 years ago.

is unlikely given consumer familiarity with both names (both names are currently used in the marketplace (Ref. 6, Vinik; Ref. 7, Wingfield and McDonald; Ref. 2, Captain Jack's Seafood Locker)). Hence, we estimate that there are zero benefits associated with an increase in the demand for the crab species *Lithodes aequispinus* as a result of changing the common or usual name of the species from "Brown King crabmeat" to "Golden King crabmeat".

In sum, and illustrated below in Table 5, we estimate that there are zero benefits associated with changing the common or usual name of *Lithodes aequispinus* from "Brown King crabmeat" to "Golden King crabmeat".

Table 5 – Total Benefits (4.5 Month Compliance Period) (in 2016$)

	Low	Mean	High
Total Benefits	$0	$0	$0

3. Option 3 – The Final Rule, But With a 1 Year Compliance Period

i. Costs

As described earlier, a change to the common or usual name or fanciful (trade) name for a food product represents a major labeling change. Hence, using the FDA Labeling Cost Model, we estimated per-sales-unit labeling costs of a major label change for the "Seafood" product category for a 1 year compliance period. These costs, which are in 2016 dollars and range from 5 cents per sales unit to 16 cents per sales unit with a mean estimate of 9 cents per sales unit, are illustrated below in Table 6.

Table 6 – Labeling Costs Per Sales Unit (1 Year Compliance Period) (in 2016$)

	Low	Mean	High
Labeling Cost Per Sales Unit	$0.05	$0.09	$0.16

As stated earlier, the total number of *Lithodes aequispinus* in this year's U.S. marketplace is 4,873,215. We estimate that there will be a relabeling cost at each of the manufacturer, wholesaler, and retailer levels associated with each of these 4,873,215 *Lithodes aequispinus* related to changing the name of the crab from Brown King Crab to Golden King Crab. Because we do not know how many, if any, of these 4,873,215 *Lithodes aequispinus* are already labeled as Golden King Crab, we conservatively estimate that all of these 4,873,215 *Lithodes aequispinus* are currently labeled as Brown King Crab and, thus, will require a label change.

The present value of the total cost of this labeling change in 2016 dollars is summarized below in Table 7 and ranges from $0.7 million to $2.3 million, with a mean estimate of $1.3 million. Using a 20 year annualization period, annualized labeling costs range from $0.05 million to $0.2 million, with a mean estimate of $0.09 million, using a 3 percent discount rate, and from $0.07 million to $0.2 million, with a mean estimate of $0.1 million, using a 7 percent discount rate (2016$).

Table 7 – Total Labeling Costs (1 Year Compliance Period) (in 2016$)

	Low	Mean	High

Manufacturer Level	$243,661	$438,589	$779,714
Wholesaler Level	$243,661	$438,589	$779,714
Retailer Level	$243,661	$438,589	$779,714
Total Labeling Costs	**$730,983**	**$1,315,767**	**$2,339,142**
Annualized (3%)	$49,134	$88,440	$157,227
Annualized (7%)	$69,000	$124,199	$220,798

Notes: There are no cost savings associated with this regulatory option. The present value of labeling costs using a 3 percent discount rate equals the present value of labeling costs using a 7 percent discount rate because relabeling costs are one time, up front costs. We estimate annualized labeling costs using Microsoft Excel's PMT function and a 20 year annualization period.

ii. Benefits

Relying on the discussion in Section F(2)(ii) of this Regulatory Impact Analysis, we estimate that there are zero benefits associated with changing the common or usual name of *Lithodes aequispinus* from "Brown King crabmeat" to "Golden King crabmeat" under this regulatory option. This is illustrated below in Table 8.

Table 8 – Total Benefits (1 Year Compliance Period) (in 2016$)

	Low	Mean	High
Total Benefits	$0	$0	$0

4. Option 4 – The Final Rule, But Which Also Allows for "Brown King crabmeat" as the Common or Usual Name for the Species *Lithodes aequispinus*

i. Costs

Under this regulatory option, a labeling change from "Brown King crabmeat" to "Golden King crabmeat" would be voluntary, since both names would be allowed. Hence, there are zero costs under this regulatory option, as illustrated below in Table 9.

Table 9 – Total Labeling Costs (both "Brown King crabmeat" and "Golden King crabmeat" allowed) (in 2016$)

	Low	Mean	High
Total Labeling Costs	$0	$0	$0

Notes: There are no cost savings associated with this regulatory option.

ii. Benefits

Relying on the discussion in Section F(2)(ii) of this Regulatory Impact Analysis, we estimate that there are zero benefits under this regulatory option, as illustrated below in Table 10.

Table 10 – Total Benefits (both "Brown King crabmeat" and "Golden King crabmeat" allowed) (in 2016$)

	Low	Mean	High
Total Benefits	$0	$0	$0

5. Summary of Costs and Benefits by Regulatory Option

Estimated costs and benefits, by regulatory option, are summarized below in Table 11.

Table 11. Summary of Costs and Benefits by Regulatory Option (in millions of 2016$)

		Present Value				Annualized		
Option	**Discount Rate**	**Benefits**	**Costs**	**Net Benefits**		**Benefits**	**Costs**	**Net Benefits**
1 – No New Federal Regulatory Action	3%	$0	$0	$0		$0.0	$0.0	$0.0
	7%	$0	$0	$0		$0.0	$0.0	$0.0
2 – Final Rule	3%	$0	$3.4	-$3.4		$0.0	$0.2	-$0.2
	7%	$0	$3.4	-$3.4		$0.0	$0.3	-$0.3
3 – Final Rule – 1 Year Compliance Period	3%	$0	$1.3	-$1.3		$0.0	$0.1	-$0.1
	7%	$0	$1.3	-$1.3		$0.0	$0.1	-$0.1
4 – Final Rule – "Brown King crabmeat" or "Golden King crabmeat" allowed	3%	$0	$0	$0		$0.0	$0.0	$0.0
	7%	$0	$0	$0		$0.0	$0.0	$0.0

Notes: There are no cost savings associated with any of these regulatory options. Benefits and costs reflect mean estimates. The present value of costs using a 3 percent discount rate equals the present value of costs using a 7 percent discount rate because costs, which are comprised solely of labeling costs, are one time and up front. Annualized amounts are estimated using Microsoft Excel's PMT function and a 20 year annualization period.

References

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[8] RTI International “2014 FDA Labeling Cost Model”, August 2015.