Regulatory Oversight

Behavioral Research

Study Protocol

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Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users

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Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users

A Introduction

A1 Study Abstract

RAI Services Company (RAIS)[1], on behalf of R. J. Reynolds Tobacco Company, intends to submit a Modified Risk Tobacco Product (MRTP) application to the U.S. Food and Drug Administration (FDA) requesting that the Agency issue a "risk modification" order for Camel SNUS. The MRTP application will propose modified risk messaging for six (6) Camel SNUS products currently marketed in the United States (collectively "Camel SNUS"). Specifically, RAIS will seek an order for the following "reduced risk" messaging on Camel SNUS:

"Smokers who switch completely from cigarettes to Camel SNUS can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

This study has been developed to support the Camel SNUS MRTP application by providing quantitative assessments of consumers'[2]:

(1) ability to understand the Camel SNUS modified risk messaging;

(2) beliefs about the health risks of using Camel SNUS relative to other tobacco products, including those within the same class of products;

(3) beliefs about the health risks of using Camel SNUS relative to cessation aids; and,

(4) beliefs about the risks of using Camel SNUS relative to quitting all tobacco use.

A2 Research Questions and Hypotheses

Comprehension

Research question: Do consumers understand the Camel SNUS modified risk messaging?

[1] RAIS is a wholly-owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for coordinating regulatory compliance for RAI's FDA-regulated operating companies, namely R. J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc.

[2] The term "consumers" is used throughout the study protocol to represent users and non-users of tobacco products.

Hypothesis: A sufficient proportion of consumers will understand the proposed Camel SNUS modified risk messaging in order to demonstrate that consumers are not mislead by that messaging.

Beliefs about Risk

Research question: What do consumers believe about the absolute health risks of using Camel SNUS, as well as those risks relative to 1) other tobacco products (e.g., cigarettes), 2) cessation aids, and 3) quitting all tobacco use?

Hypothesis: A sufficient proportion of consumers will believe that 1) Camel SNUS use carries some health risks (versus no risk); 2) the health risks associated with using Camel SNUS are reduced relative to cigarette smoking; and 3) the health risks associated with using Camel SNUS are greater than the risks associated with using cessation aids or quitting all tobacco use.

B Background

B1 Rationale for the Study

RAIS is in the process of developing an application to FDA seeking an order to market Camel SNUS as an MRTP. A key component of that marketing application will be a demonstration that consumers understand, and are not mislead, by the messages used to promote Camel SNUS as an MRTP. More specifically, Congress has mandated that *"any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products*[3]*."* In essence, then, the mandate requires that consumers comprehend that Camel SNUS, marketed as a modified or reduced risk tobacco product, still bears at least *some* of the risk associated with traditional tobacco products (i.e., that "reduced risk" is not the same as *no* risk), and that Camel SNUS use is associated with a greater risk to health than using smoking cessation products or quitting all tobacco use.

Consideration for this research began with a thorough review of FDA's draft guidance document, "Guidance for Industry: Modified Risk Tobacco Product

[3] Food and Drug Administration (FDA). (2012). *Section 911 of the Federal Food, Drug, and Cosmetic Act – Modified Risk Tobacco Products.* Retrieved from http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm262077.htm

Applications"[4] and the Institute of Medicine Report, "Scientific Standards for Studies on Modified Risk Tobacco Products"[5]. For example, FDA's draft guidance to the industry recommends that applicants provide evidence from scientific studies on consumer comprehension and perceptions; specifically, the ability of consumers to understand the modified risk claims and the significance of that information in the context of one's health; consumers' beliefs about the health risks of using the MRTP relative to other tobacco products, including those within the same class of products; consumers' beliefs about the health risks of using the MRTP relative to cessation aids; and, consumers' beliefs about the risks of using the MRTP relative to quitting all tobacco use.

B2 Prior Literature and Studies

Development of this protocol is based on extensive experience developing and implementing numerous Risk Evaluation and Mitigation Strategy (REMS) surveys (administered on behalf of pharmaceutical clients in order to assess comprehension of the risks and benefits of pharmaceutical products) and FDA's "Guidance for Industry: Label Comprehension Studies of Nonprescription Drug Products" published in August 2010 by the Center for Drug Evaluation and Research (CDER)[6]. In addition, literature that addresses health risk beliefs of different types of tobacco products (e.g., Haddock, Lando, Klesges, Peterson and Sarinci, 2004; O'Connor, Hyland, Givono, Fong and Cummings, 2005; and Peiper, Stone, Van Zyl and Rodu, 2010)[7] has informed current thinking with regard to how best to pose key health risk belief questions. Finally, protocol development has been informed by the following preliminary studies designed to assess the proposed modified risk messaging:

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[4] Food and Drug Administration (FDA). (2012, March). *Guidance for Industry: Modified Risk Tobacco Product Applications: Draft Guidance.* Retrieved from http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf

[5] Institute of Medicine (IOM). (2011, December 14). *Scientific Standards for Studies on Modified Risk Tobacco Products.* Washington, DC: National Academy of Sciences.

[6] Food and Drug Administration (FDA). (2010, August). *Guidance for Industry: Label Comprehension Studies of Nonprescription Drug Products.* Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM143834.pdf

[7] Haddock, C. K., Lando, H., Klesges, R. C., Peterson, A. L., & Scarinci, I. C. (2004). Modified tobacco use and lifestyle change in risk-reducing beliefs about smoking. *American Journal of Preventive Medicine*, *27*(1), 35-41; O'Connor, R. J., Hyland, A., Giovino, G. A., Fong, G. T., & Cummings, K. M. (2005). Smoker awareness of and beliefs about supposedly less-harmful tobacco products. *American Journal of Preventive Medicine*, *29*(2), 85-90; Peiper, N., Stone, R., Van Zyl, R., & Rodu, B. (2010). University faculty perceptions of the health risks related to cigarettes and smokeless tobacco. *Drug and Alcohol Review*, *29*(2), 121-130.

- A series of focus groups, comprised of current adult tobacco users only, designed to provide feedback regarding different versions of the proposed modified risk messaging. *(see Attachments, "Preliminary Qualitative Brand Research Reports")*
- Two rounds of in-person research among adult consumers in each of the three major tobacco user groups of interest (i.e., current, former and never tobacco users) to assess comprehension of the modified risk messaging developed from the initial research among tobacco users. Following each round, both the proposed messaging and the questions for assessing comprehension were modified. *(see Attachment, "Camel SNUS MRTP Preliminary Research on Consumer Comprehension and Perceptions Report")*
- Two small, online quantitative surveys conducted among tobacco user groups of interest (i.e., current, former and never tobacco users, as well as potential quitters and experimenters) to assess comprehension of the modified risk messaging in the environment in which data will ultimately be collected. *(see Attachment, "Camel SNUS MRTP Preliminary Research on Consumer Comprehension and Perceptions Report")*

C Study Objectives

C1 Primary Aims

1. Comprehension
    - Demonstrate that consumers, overall and within key sub-groups (i.e., current, former, never and experimental tobacco users, as well as potential quitters, minorities, low literacy respondents and white males), understand the following key communication objectives of the proposed Camel SNUS modified risk messaging:
        (a) those who do not use tobacco products should not start;
        (b) for current tobacco users, the best option is to quit all tobacco products;
        (c) there are risks associated with using Camel SNUS, but those risks are reduced compared to cigarette smoking;
        (d) smokers who use Camel SNUS instead of cigarettes can significantly reduce their risks for smoking-related disease; and
        (e) Camel SNUS is addictive.

2. Beliefs about risk

   - Assess consumers' beliefs regarding the absolute health risks associated with using Camel SNUS, as well as those risks relative to other tobacco products (i.e., cigarettes and other smokeless tobacco products), cessation aids, and quitting all tobacco use.

C2 Rationale for the Selection of Outcome Measures

The outcome measures were created based on principles published in *"Guidance for Industry: Label Comprehension Studies of Nonprescription Drug Products"* by FDA's Center for Drug Evaluation and Research (CDER). These measures were also based on details included in the FDA's draft guidance document, *"Guidance for Industry: Modified Risk Tobacco Product Applications"*[8]. They were created to maximize validity, and evaluated in previous research to maximize clarity and minimize bias. *(see Attachment, "Camel SNUS MRTP Preliminary Research on Consumer Comprehension and Perception Report")*

C3 Research Stimuli

The research stimuli for the quantitative research will be high resolution color images of a Camel SNUS MRTP advertisement that includes modified risk messaging. The advertisement will include images and information for the entire Camel SNUS family (two pouch sizes, regular and large; and, five styles including Frost, Mint, Mellow, Robust and Winterchill). In addition, the four different mandated warning labels will be presented. Each respondent will be shown the Camel SNUS MRTP advertisement, and will be randomly assigned to view one of the four mandated warnings. The warning labels will cover at least 20% of the area of each image or page of the advertisement. This design mimics the environment in which the advertisement would appear in the marketplace and is, therefore, the recommended design.

The research stimuli images are provided in *Appendix B, "Camel SNUS MRTP Comprehension and Perception Stimuli."*

[8] Food and Drug Administration (FDA). (2012, March). *Guidance for Industry: Modified Risk Tobacco Product Applications: Draft Guidance.* Retrieved from http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf

D Study Design

D1 Overview or Design Summary

A. Data Collection Procedures

Research Now will send email invitations to a random subset of panel members who belong to the target population of U.S. adults who are legally eligible to purchase tobacco (as legislated by the states in which they reside). Each invitation will contain a generic survey title ("Get Rewarded for Your Time – Study about Consumers"), the length of the survey, incentive amount provided for successful completion of the survey, and instructions for accessing the secure website for the survey, to be hosted by **NA**XION. Once a panel member enters the secure web site, a brief introduction will be presented informing the panel member of the private and voluntary nature of the survey. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL. Panel members who choose to participate will answer a few qualifying questions necessary to monitor quotas.

B. Survey Content and Structure

The survey itself *(refer to Appendix A: "Camel SNUS MRTP Comprehension and Perception Survey")* will consist of three main elements:

- An assessment of **comprehension** of the Camel SNUS modified risk messaging. The comprehension test will appear on the same screen directly beneath the advertisement, allowing respondents to scroll back and forth, as desired.
- Ratings of health risk **beliefs** on a 7-point scale. Each respondent will rate the risk of experiencing various types of harm (e.g., oral cancer, lung cancer, heart disease, etc.) associated with smoking cigarettes, using Camel SNUS, and using other smokeless tobacco. In addition, they will be asked for beliefs of the health risks associated with using Camel SNUS relative to using cessation aids and quitting all tobacco use.
- The Newest Vital Sign (NVS)[9] health literacy test, the results of which will be used to compare results among "adequate" and "limited" literacy level consumers. The NVS is a reliable and accurate measure of literacy that can identify respondents with limited literacy. The NVS uses a nutrition label from an ice cream container, and is a 6-item test that assesses the respondent's

[9] Annals of Family Medicine. (2005, November). *Quick Assessment of Literacy in Primary Care: The Newest Vital Sign.* Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1466931/

ability to read and apply information from the nutrition label. The respondent receives one point for each question correctly answered, which results in a maximum total score of six points. Respondents will be classified into one of two categories based on their scores:

1) Limited literacy (score of 0-3)

2) Adequate literacy (score of 4-6)

D2 Subject Selection and Withdrawal

A. Inclusion Criteria

U.S. adults who are legally eligible to purchase tobacco products (as legislated by the states in which they reside), and who are members of the Research Now panel.

B. Exclusion Criteria

Individuals who are not old enough to purchase tobacco products legally. Research Now will only invite English-speaking consumers because Camel SNUS messaging and advertising materials are expected to be in English only.

In addition, Research Now is constantly managing panel members labeled as "professional survey takers" or "gamers." Research Now has an extensive process in place to track and remove members who have proven in previous surveys that they are not taking surveys properly. Research Now checks for members who are speeding, entering gibberish into open-ended questions, and failing "traps" programmed into some surveys in order to identify whether the member should be flagged. If a member continually exhibits "bad behavior", Research Now flags them. The respondents that are flagged for a propensity for bad survey behavior will then receive only dummy surveys moving forward, i.e., until they show that they are able to properly take surveys. If they exhibit the bad behavior on the dummy surveys, then they are removed from the panel. If they do well with the dummy surveys (exhibiting "good behavior"), then they are reactivated and put back in the panel.

Finally, Research Now also has a continuous process in place that allows respondents to "rest." Panel members set the number of survey invitations they would like to receive per week when they enroll in the panel. Once that limit is reached, they are deemed "resting" and not available for surveys until their frequency limiters are reset. These limiters allow Research Now to maintain their panelists and keep them engaged.

Ethical Considerations and Respondent Disclaimer

Panel membership and survey participation are both entirely voluntary. To minimize the prospect that consumers perceive the survey to be an inducement to use tobacco, the following statement will appear at the end of the survey:

"Please note that the goal of this survey is only to assess how clear the communication of risk is, on tobacco products, to people from many different backgrounds. It is ***not*** *intended to encourage you or anyone else to continue or start using tobacco products."*

- *Individuals should consider the conclusions of the U.S. Surgeon General, as well as information from the Centers for Disease Control and Prevention, and other public health and medical officials when making decisions regarding smoking.*
- *The best course of action for tobacco users concerned about their health is to quit.*
- *Minors should never use tobacco products and adults who do not use or have quit using tobacco products should not start.*
- *Adults who smoke should avoid exposing minors to secondhand smoke, and adult smokers should comply with rules and regulations designed to respect the rights of other adults.*

All information contained in this advertising is provided for your information only and for regulatory research purposes only. In order to advertise that a smokeless tobacco product is less harmful than a cigarette or another smokeless tobacco product, the company must first obtain clearance from the Food and Drug Administration ("FDA"). As part of that clearance process, a company must present evidence demonstrating that consumers perceive and understand the statements that the company is making about the product in its proposed advertising. This research is aimed at developing advertising that will achieve this. The advertisements used in this research study have not and will not be used by the company to promote its products commercially without first obtaining clearance from FDA to do so.

The information and opinions expressed here are believed to be accurate, based on sound science and the best judgment available to the company. However, no action or inaction should be taken based on the contents of this information; instead, you should consult appropriate health professionals on any matter relating to your health."

C. Subject Recruitment Plans and Consent Process

Members of the Research Now national consumer online panel, a demographically balanced panel with over three million members from all 50 states in the United States and the District of Columbia (DC)[10], will receive an email inviting them to participate in screening for the survey. Those who agree to participate will proceed to answer a few qualifying questions.

D. Randomization Method and Blinding

Invitations will be sent to a random sample from the Research Now panel. The survey will not be blinded.

E. Risks and Benefits

We do not perceive there to be any risks associated with participating in this study, but all respondents will be shown a disclaimer at the conclusion of the survey in order to mitigate the possibility that consumers perceive the survey to be an inducement to use tobacco. Respondents will receive a nominal benefit from Research Now for participating in this study (*see section I2 for rewards/reimbursement details*).

E Study Procedures

E1 Screening for Eligibility

The sampling frame for the study is all U.S. adults who are legally eligible to purchase tobacco products (as legislated by the states in which they reside). Although Camel SNUS MRTP advertising is expressly intended for people who are adult tobacco users, the research intends to assess the comprehension of key messages in the MRTP advertising among all adults. Due to concerns about showing tobacco products to minors and consistent with RAIS policy, we do not intend to draw a sample of consumers below the legal age for purchasing tobacco products.

The survey will use a convenience sample drawn from the Research Now national consumer online panel, a demographically balanced panel with over three million members from all 50 states and DC. Historically, survey research relied on probability sampling to justify the use of parametric statistics (e.g., to allow

[10] Because the sample will be balanced by US Census Region, respondents on Research Now's panel from the Pacific Islands and other territories such as American Samoa, Armed Forces Europe, Armed Forces Pacific, Federated States of Micronesia, Palau, Northern Mariana Islands, Virgin Islands, and Puerto Rico will not be included in the sample.

calculation of a statistical confidence interval). But non-probability samples are today both commonplace and widely accepted in light of the acknowledged challenges of drawing true probability samples and the belief that with appropriate care, it is legitimate to use well-designed non-probability samples to represent the population at large (*for a discussion, see The Journal of Survey Statistics and Methodology, November 2013*). Although we will be unable to generalize our findings to individuals who do not use the internet, we have no reason to believe that their understanding of communication materials for tobacco products will be sufficiently different from the demographically similar internet panel users to have a material effect on the research outcome.

All sampled panel members who, upon receiving an email invitation, agree to proceed through the survey screening will answer a few qualifying questions designed to monitor quotas developed to maximize representativeness of the sample with respect to basic demographic parameters (e.g., smoking behavior, age, gender, education and ethnicity/race) and facilitate weighting of the data to match the U.S. population at-large. Note that it will not be possible to *quota-sample* based on literacy level because the one validated health literacy test that can be administered on-line (i.e., NVS) could create bias by "priming" respondents to read subsequent material in a way that they otherwise might not. We do, however, propose to include the NVS health literacy test at the end of the survey, which will allow data to be analyzed by literacy level. A copy of the proposed screener, eligibility criteria, and quotas is provided as *Appendix A*.

E2 Sampling Plan

Upon completion of the screener, consumers will be classified into one of three tobacco user groups:

1) Current user: have ever used tobacco (even once or twice), meet historical usage requirements (i.e., lifetime usage for cigarettes or ever fairly regular use for all other tobacco products) for at least one tobacco product, and now use tobacco "every day" or "some days" *(see survey document in Appendix A)*;

2) Former user: have ever used tobacco (even once or twice), meet historical usage requirements for at least one tobacco product, but do not currently use tobacco at all; or,

3) Never user: have never used any tobacco (even once or twice).

In addition, Current Users will be asked a series of questions to identify "potential quitters". The survey questions used to determine potential quitters are from the FDA's Graphic Warning Label study. Potential quitters, for this study, are defined

as current users who answer the quit-related questions, as follows (with survey questions noted):

1) Has stopped using tobacco for one day or longer in the past 12 months in an effort to quit tobacco completely (S1f); AND
2) Indicate they want to quit using tobacco "somewhat" or "a lot" (S1g); AND
3) Rate the likelihood of trying to quit tobacco in the next 30 days as "somewhat likely" or "very likely" (S1h); AND
4) Rate the likelihood that, if an attempt was made to quit tobacco, they would be "somewhat" or "very" successful in quitting (S1i).

Finally, some consumers will be defined as "experimenters" if they meet the following requirements (survey questions and definitions based on FDA's Population Assessment of Tobacco and Health study):

1) Have ever used a tobacco product (even once or twice);
2) Do not meet historical tobacco product tobacco-use thresholds; and,
3) Currently use tobacco "every day" or "some days".

Some of these tobacco user groups are not mutually exclusive (e.g., a consumer could be a current cigarette user and a former SNUS user); therefore, a hierarchy was established in order to place consumers into one tobacco user group only for purposes of quota-sampling, survey arm balancing, and analyses. The hierarchy is organized in the following manner:

1) Never user
2) Current user
3) Experimenter
4) Former user

Never users are first in the hierarchy because they represent a mutually exclusive tobacco user group. Current users have second priority because they are a key group of interest. Experimenters precede former users because (1) they are a group of particular concern and (2) they are a group that is harder to identify versus the other tobacco user groups.

If initial recruiting efforts do not provide a readable sample from sub-groups most likely to be affected positively or negatively by the Camel SNUS modified risk messaging, additional sample will be released to ensure a minimum of 100

respondents in each of the following sub-groups[11]:

- Current tobacco users (including potential quitters)
- Non-tobacco users (including former and never tobacco users)
- Experimenters (will be used as a proxy for "youth" respondents)
- Minority (defined as non-Caucasian) respondents
- White males
- Respondents with "limited literacy". Literacy will be assessed using an on-line test of health literacy (i.e., NVS) that has been used in FDA-commissioned studies.[12]

Within in each quota cell (represented by the combination of tobacco user group and demographics), respondents will be randomly assigned to view one of the four mandated warnings.

F Statistical Plan

F1 Sample Size Determination and Power

The total sample size for this study will be approximately 7,500 consumers (i.e., tobacco users and non-users). This sample size is driven by a desire to have a sufficiently large sample in each of the three tobacco user groups – current, former and never tobacco users – to allow for quota-sampling by combinations of demographic variables (e.g., age groups within the ethnicities and geographic regions).

This sample size is sufficient to allow the data to be weighted to population counts for all parameters of interest in each of the three tobacco user groups, on the following dimensions (*see Appendix A, Table 1 for details*):

(a) Age: 30 years old or younger, 31 to 50 years old, and 51 years and older

(b) Ethnicity: Hispanic, non-Hispanic

(c) Race: Caucasian, African American, Asian/Other

(d) Gender: male, female

[11] Letter from FDA re May 29 Meeting Minutes: Submission Tracking Number (STN): TC0001068. 2014, June 25.

[12] Annals of Family Medicine. (2005, November). *Quick Assessment of Literacy in Primary Care: The Newest Vital Sign.* Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1466931/

(e) Education Level: up to high school, some college, bachelor's degree or more

(f) Geography: Northeast, South, Midwest, West

The following table provides estimates of the 95% confidence intervals for different levels of comprehension performance that represent the anticipated range of responses and various sample sizes likely to be used in sub-group analyses:

	Comprehension and Perception Closed-end Questions				7-point ratings
Sample Size	60% Correct	70% Correct	80% Correct	90% Correct	St. dev. = 2.0
7,500	+/- 1.1%	+/- 1.0%	+/- 0.9%	+/- 0.7%	+/- 0.05
5,000	+/- 1.4%	+/- 1.3%	+/- 1.1%	+/- 0.8%	+/- 0.06
2,500	+/- 1.9%	+/- 1.8%	+/- 1.6%	+/- 1.2%	+/- 0.08
1,000	+/- 3.0%	+/- 2.8%	+/- 2.5%	+/- 1.9%	+/- 0.12
500	+/- 4.3%	+/- 4.0%	+/- 3.5%	+/- 2.6%	+/- 0.18
100	+/- 9.6%	+/- 9.0%	+/- 7.8%	+/- 5.9%	+/- 0.39

F2 Analysis Plan

A. Data Weighting

Data will be weighted to account for quota sampling (*see quota groups listed in Table 1 of Appendix A*). In preparation for weighting, population counts will be developed to estimate the number of individuals in each cell represented by the intersection of geographic region, tobacco use status, and age. The weighting process will then consist of:

- Developing ***base weights*** by dividing the number of completed interviews in the cells that represent the intersection of geographical region, tobacco use status, and age by the following population counts in those cells.
- Adjusting the base weights using ***raking*** to weight up to population counts in cells represented by the intersection of the following parameters:

  (a) Region, tobacco status and gender

  (b) Region, tobacco status and ethnicity

(c) Region, tobacco status and education

(d) Region, tobacco status and age

(e) Region, age and ethnicity

Raking[13] helps to account for undercoverage and other sources of bias by adjusting the individual weights that result from the previously applied steps to independent estimates of population parameters from the Census Bureau's Population Estimates Program, the Annual Social and Economic Supplement to the Current Population Survey (CPS), and the Tobacco Use Supplement to the Current Population Survey[14].

B. Analysis of Comprehension Data

Analysis of the comprehension questions will focus on the distribution of responses and mean percent correct (with a two-tailed 95% confidence interval) for each item in the comprehension test battery for the sample overall, and sub-groups of interest (i.e., current, former, never and experimental tobacco users, as well as potential quitters, minorities, low literacy respondents and white males).

There is no published standard for an acceptable level of comprehension required to market a product, making it inappropriate to set a level of performance that must be met for every question for the sample overall and for every sub-group.

C. Analysis of Health Risk Belief Ratings

Risk belief data will be analyzed for the sample overall and sub-groups of interest to address the following hypotheses:

- Ratings of health risks will provide evidence that consumers have *not* been misled by the proposed modified risk messaging for Camel SNUS, and continue to believe Camel SNUS is associated with some health risks and is addictive.
- Mean ratings for Camel SNUS will be lower than cigarettes for some health conditions and diseases.

D. *Analysis of Belief Data: Use of Cessation Aids and Quitting Tobacco Entirely*

The mean percent correct responses (within two-tailed 95% confidence intervals) for the following items will be calculated: (1) the risk of using Camel SNUS *relative*

[13] Michael P. Battaglia, David Izrael, David C. Hoaglin, and Martin R. Frankel, Survey Practice, June 2009. "Practical Considerations in Raking Survey Data."

[14] "Improving Survey Methodology," Office of Surveillance, Epidemiology, and Laboratory Services, Behavioral Risk Factor Surveillance System, Centers for Disease Control and Prevention.

to using cessation aids, and (2) the risk of using Camel SNUS *relative* to quitting tobacco entirely. Once again, the absence of a published standard makes it inappropriate to set a level of performance that must be met for this type of question.

F3 Statistical Methods

Differences between risk beliefs for different types of tobacco products will be assessed using traditional parametric statistics (i.e., ANOVA and t-tests). Because Research Now uses probability sampling when inviting panel members to be screened for survey participation, it is appropriate to use inferential statistics, based on the understanding that assumptions must be made to extrapolate beyond the population of panel members.

G Data Handling and Record Keeping

G1 Confidentiality and Security

NAXION is an ISO 20252:2012 certified company. As such, we comply with documented procedures with regard to confidentiality and security.

Regarding confidentiality, **NA**XION will only entrust survey data with other entities when: 1) the participant gives explicit permission to release this data; 2) the data is shared with an entity who agrees in writing that the data will be held strictly confidential and that the data will be used for research purposes only; or, 3) the release of this data is required by law. This assurance is shown to survey participants before they provide any survey data. They may refuse to participate in the survey as a consequence if they wish.

Participants are also shown an active link to **NA**XION's privacy policy.

No respondent-identifiable information (e.g., name, date of birth, address, phone number, or social security number) will be available to **NA**XION; thus, respondents' identities will never be made known to RAIS.

Data is held securely and in compliance with client instructions and professional codes. Electronic documents are backed up from the network, and at least one copy of the network backups are stored offsite.

Additionally, we adhere to the following:

- All critical systems are backed up;
- Backups are periodically tested;

- Virus protection software is effective and current;
- Data on laptops are not shared across staff members; and,
- Memory sticks are encrypted and cleared between use by different staff members.

Items above are audited by a third party on an annual basis.

G2 Training

NAXION employees are initially trained by being assigned to tasks that are reviewed by a more experienced employee. For example, a new employee may write a part of a survey which will be reviewed by another employee with sufficient experience to write the survey himself/herself. In the event that formal training is conducted, that training will be recorded by Human Resources on the personnel record. Employees keep a record of the in-house training sessions they have attended.

Otherwise, training needs are primarily identified via performance appraisals. These appraisals are completed by the staff member's supervisor. Training needs are clearly identified. Performance appraisals are conducted at least once per year for staff members below the Group Director level. During the first year of employment, there are also 3-month and 6-month performance evaluations.

G3 Records Retention

NAXION stores its documents in compliance with its clients' requirements. For RAIS, records are stored indefinitely.

Research records will be retained such that a project could be replicated in the future, as necessary, including primary records and supporting records (which include research process management system records). Records will be retained securely and in such a way that they are safe from damage. Electronic records will be backed up, and at least one copy will be stored offsite.

G4 Performance Monitoring

On an annual basis, the Research Process Management System (**NA**XION's internal performance monitoring system) is reviewed by the Quality Manager, COO, and CEO to determine:

- Its business effectiveness;
- Compliance to processes within the company;
- Need for change or improvement; and,

- That it continues to meet industry standards and legal and regulatory requirements

H Study Monitoring, Auditing and Inspecting

H1 Study Monitoring Plan

Throughout field, **NA**XION will monitor the number of completed surveys in each quota cell/group daily via a proprietary online reporting system. Survey sampling adjustments can then be made on an ongoing basis to help achieve the desired number of completed surveys in each quota cell.

Experience with online tobacco research suggests that about 15% of those who are sent survey invitations will complete a study. **NA**XION will implement several procedures to maximize participation. We will keep the study questionnaire at a reasonable length to minimize break-offs. Additionally, the following procedures will be used to maximize cooperation and to achieve the desired response rates:

- Research Now will provide toll-free telephone numbers to all sampled individuals, and invite them to call with any questions or concerns about any aspect of the study. **NA**XION will provide a toll-free telephone number and email address for a **NA**XION project member should participants have any questions about the study or their rights as a study participant.
- The staff of Research Now will work with the project staff of **NA**XION to address any problems that arise throughout the course of data collection.

Invited panel members who do not visit the site for screening will receive one e-mail reminder from Research Now requesting their participation in the survey. These "reminder" emails will be sent roughly one week after the initial survey invites are sent.

H2 Auditing and Inspecting

NAXION project managers and other **NA**XION employees will thoroughly test the programmed questionnaire, along with any algorithms for sampling before the survey is launched via the Internet. **NA**XION will also have live online reports that show the number of completed surveys throughout field. Reports will run every hour, and will detail completed surveys by tobacco user group and demographic characteristics. These reports allow **NA**XION project managers to ensure that the sampling algorithm is operating as planned throughout the fielding process, and that the desired tobacco-user group and demographics are attained.

I Study Administration

I1 Organization and Participating Centers

NAXION will manage the information collection on behalf of RAIS, process the data, and perform all statistical analyses. Michael Polster, Ph.D. is the project director at **NA**XION, with overall responsibility for coordinating study activities. He will be working under the leadership of the firm's CEO. **NA**XION Worldwide will subcontract to Research Now to collect the survey data.

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I2 Subject Stipends or Payments

Research Now panel members earn currency or points for their time participating in surveys. Incentives are based on estimates of the time and effort required to complete a survey. Members can redeem their currency/points for rewards that are of interest to them. Providing every panel member with an incentive for each interaction helps maximize panel retention and survey response rates.

I3 Study Timetable

We estimate that this study will require approximately ten weeks to complete, according to the following timeline:

PROPOSED TIMETABLE

Draft Survey	Week 1
Programming and Pretest	Weeks 2 and 3
Survey Fielding	Weeks 4, 5, and 6

Data Analysis and Report Writing.....	Weeks 7, 8, and 9
Final Report Available.....	Week 10

J Publication Plan

Data will be made available as part of the MRTP application process to FDA.

Appendix A: Camel SNUS MRTP Comprehension and Perception Survey

Research conducted on behalf of RAIS in anticipation of potential FDA submissions. Research shall only be used and/or disseminated for regulatory-related activities.

Camel SNUS MRTP Comprehension and Perceptions Survey
- Screener –

Thank you for visiting our survey site to answer a few qualifying questions. This survey is strictly for research purposes only.

It is NAXION's policy to keep interviews anonymous and responses confidential. Consistent with this policy, NAXION will only entrust survey data with other entities when: 1) the participant gives explicit permission to release this data, or 2) the data is shared with an entity who agrees in writing that the data will be held strictly confidential and that the data will be used for research purposes only, or 3) the release of this data is required by law.

You will not be contacted for sales purposes as a result of participating in this survey.

For further information on NAXION's privacy policy, you can view our website at www.naxionthinking.com/privacy-policy/privacy-policy-domestic-and-global-information. To view our respondent incentive statement, visit www.naxionthinking.com/incentivestatement.

All questions on each screen must be answered before you move to the next screen, so please be sure you have answered every question before trying to move forward. On the next few screens you will be asked a few questions to see if you qualify for this study. If you qualify, the survey itself should take less than 15 minutes to complete.

PROGRAMMER:

1) **INSERT STANDARD INSTRUCTION SCREEN**
2) **THIS IS A 4-ARM SURVEY WITH ARMS BALANCED ON TOBACCO STATUS (CURRENT, FORMER, NEVER), TYPE OF TOBACCO USED (SNUS AND CAMEL SNUS), DEMOGRAPHICS, EXPERIMENTER, AND POTENTIAL QUITTER**

FIELD OPS: RECRUIT RESPONDENTS FROM ONLY "TRADITIONAL" RESEARCH NOW PANEL
DO NOT ALLOW SURVEY TO BE TAKEN VIA iPHONE/BLACKBERRY, etc.
HAVE RECRUITERS DRAW SAMPLE…

1) **ACCORDING TO MINIMUM PURCHASE AGE IN STATE (SEE S7 INSTRUCTIONS)**
2) **ACCORDING TO QUOTA**
3) **NOTE THAT NO STATES ARE EXCLUDED**

S2. What is your current age?

_____ Years

PROGRAMMER:

1. **RANGE IS 10-99**
2. **IF < 18, TERMINATE NOW**

S7. In what state do you currently reside?

[SHOW POP UP LIST OF STATES]

PROGRAMMER:

1. **IF STATE IS ALABAMA, ALASKA, NEW JERSEY OR UTAH AND S2= 18, TERMINATE NOW**
   (Minimum age for tobacco purchase in these states is 19)
2. **NOTE THAT RESPONDENTS IN ALL 50 US STATES AND DC ARE ELIGIBLE TO PARTICIPATE IN THIS STUDY**

S1a1. Have you ever used any of the following tobacco products, even one or two times?

(Select "yes" or "no" for each row)

		Yes	No
1	Cigarettes	o	o
2	Roll-your-own Cigarettes	o	o
3	E-cigarettes	o	o
4	Tobacco Heating Cigarettes	o	o
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	o	o
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	o	o
7	Traditional Cigars	o	o
8	Pipe Tobacco	o	o
9	Hookah (WHO-kah)	o	o
10	Smokeless Tobacco, like dip, chew, or snuff	o	o
11	SNUS (SNOOS) Pouches	o	o
12	Dissolvable tobacco	o	o
13	Other tobacco product	o	o

PROGRAMMER:

1) ASK ALL

S1a2. Have you ever used any of the following tobacco product(s) fairly regularly?

(Select "yes" or "no" for each row)

		Yes	No
1	Cigarettes	o	o
2	Roll-your-own Cigarettes	o	o
3	E-cigarettes	o	o
4	Tobacco Heating Cigarettes	o	o
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	o	o
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	o	o
7	Traditional Cigars	o	o
8	Pipe Tobacco	o	o
9	Hookah (WHO-kah)	o	o
10	Smokeless Tobacco, like dip, chew, or snuff	o	o
11	SNUS (SNOOS) Pouches	o	o
12	Dissolvable tobacco	o	o
13	Other tobacco product	o	o

PROGRAMMER:

1) **ASK IF ANY ROW IN S1a1 IS "YES"**
2) **ONLY SHOW ROWS THAT ARE "YES" IN S1a1**

S1b. How many cigarettes have you smoked in your entire life? A pack usually has 20 cigarettes in it. *Select one.*

1	1 or more puffs but never a whole cigarette	o
2	1 to 10 cigarettes (about ½ pack total)	o
3	11 to 20 cigarettes (about ½ pack to 1 pack)	o
4	21 to 50 cigarettes (more than 1 pack but less than 3 packs)	o
5	51 to 99 (more than 2 ½ packs but less than 5 packs)	o
6	100 or more cigarettes (5 packs or more)	o

PROGRAMMER:

1) ASK IF S1a1 ROW 1 = "YES"

S1c. Please indicate how often you currently use each of the following types of tobacco.
Select one response in each row.

		Every Day	Some Days	Not at All
1	Cigarettes	o	o	o
2	Roll-your-own Cigarettes	o	o	o
3	E-cigarettes	o	o	o
4	Tobacco Heating Cigarettes	o	o	o
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	o	o	o
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	o	o	o
7	Traditional Cigars	o	o	o
8	Pipe Tobacco	o	o	o
9	Hookah (WHO-kah)	o	o	o
10	Smokeless Tobacco, like dip, chew, or snuff	o	o	o
11	SNUS (SNOOS) Pouches	o	o	o
12	Dissolvable tobacco	o	o	o
13	Other tobacco product	o	o	o

PROGRAMMER:

1) **ASK IF ANY ROW IS "YES" IN S1A1**
2) **SHOW ROWS THAT ARE "YES" IN S1A1**

PROGRAMMER TO CLASSIFY RESPONDENTS AS FOLLOWS:

DEFINE AS NEVER USER IF:

- **S1a1 is "NO" FOR ALL ROWS**

IF DO NOT QUALIFY AS NEVER USER, DEFINE AS CURRENT CIGARETTE USER IF:

- **S1a1 ROW 1 (Cigarettes) IS "Yes" AND**
- **S1b IS ROW 6 (100+ Cigarettes) AND**
- **S1c ROW 1 (Cigarettes) IS "EVERY DAY" OR "SOME DAYS"**

IF DO NOT QUALIFY AS NEVER OR CURRENT CIGARETTE USER, DEFINE AS CURRENT TOBACCO USER (NON-CIGARETTE) IF:

- **S1a1 ROW 2 IS "YES" AND**
- **S1a2 ROW 2 IS "YES" AND**
- **S1c ROW 2 IS "EVERY DAY" OR "SOME DAYS"**
- **CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS CIGARETTE EXPERIMENTER IF:

- **S1a1 ROW 1 IS "YES" AND**
- **S1b IS NOT ROW 6 (100+ CIGARETTES) AND**
- **S1c ROW 1 IS "EVERY DAY" OR "SOME DAYS"**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS NON-CIGARETTE EXPERIMENTER IF:

- **S1a1 ROW 2 IS "YES" AND**
- **S1a2 ROW 2 IS "NO" AND**
- **S1c ROW 2 IS "EVERY DAY" OR "SOME DAYS"**
- **CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS FORMER CIGARETTE USER IF:

- **S1a1 ROW 1 IS "YES" AND**
- **S1b IS ROW 6 (100+ Cigarettes) AND**
- **S1c ROW 1 IS "NOT AT ALL"**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS FORMER TOBACCO USER (NON-CIGARETTE) IF:

- **S1a1 ROW 2 IS "YES" AND**
- **S1a2 ROW 2 IS "YES" AND**
- **S1c ROW 2 IS "NOT AT ALL"**
- **CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS FORMER CIGARETTE EXPERIMENTER IF:

- **S1a1 ROW 1 IS "YES" AND**
- **S1b IS NOT ROW 6 (100+ CIGARETTES) AND**
- **S1c ROW 1 "NOT AT ALL"**

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS FORMER NON-CIGARETTE EXPERIMENTER IF:

- **S1a1 ROW 2 IS "YES" AND**

- S1a2 ROW 2 IS "NO" AND
- S1c ROW 2 IS "NOT AT ALL"
- CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES

QUOTA GROUPS:

1) CURRENT USERS =
    a. CURRENT CIGARETTE USERS
    b. CURRENT TOBACCO USERS (NON-CIGARETTE)
2) FORMER USERS =
    a. FORMER CIGARETTE USERS
    b. FORMER TOBACCO USERS (NON-CIGARETTE)
    c. FORMER CIGARETTE EXPERIMENTERS
    d. FORMER NON-CIGARETTE EXPERIMENTERS
3) NEVER USERS
4) EXPERIMENTERS =
    a. CIGARETTE EXPERIMENTERS
    b. NON-CIGARETTE EXPERIMENTERS

WE WILL BE BALANCE ARMS ON SNUS USERS (CURRENT OR FORMER): HERE IS HOW TO DEFINE THESE GROUPS:

CURRENT SNUS USER IS:

a) S1a1 ROW 11 IS "YES" AND
b) S1a2 ROW 11 IS "YES" AND
c) S1c ROW 11 IS "EVERY DAY" OR "SOME DAYS"

FORMER SNUS USER IS:

a) S1a1 ROW 11 IS "YES" AND
b) S1a2 ROW 11 IS "YES" AND
c) S1c ROW 11 IS "NOT AT ALL"

Has used Camel SNUS (S9 ROW 1 is "YES")

S1d. During the past 12 months, have you stopped using tobacco for one day or longer because you were trying to quit using tobacco? *Select one.*

Yes	o
No	o

PROGRAMMER:

1) ASK CURRENT USERS

S1e. How much do you want to quit using tobacco? *Select one.*

Not at all	o
A little	o
Somewhat	o
A lot	o
No opinion	o

PROGRAMMER:

1) ASK CURRENT USERS

S1f. How likely do you think it is that you will try to quit using tobacco within the next 30 days?

Select one.

Very unlikely	o
Somewhat unlikely	o
Somewhat likely	o
Very likely	o
No opinion	o

PROGRAMMER:

1) ASK CURRENT USERS

S1g. If you did try to quit using tobacco within the next 30 days, how likely do you think it is that you would succeed in quitting? *Select one.*

Very unlikely	o
Somewhat unlikely	o
Somewhat likely	o
Very likely	o
No opinion	o

PROGRAMMER:

1) ASK CURRENT USERS

CLASSIFY RESPONDENT AS POTENTIAL QUITTER IF:

- **S1D = YES AND**
- **S1E = SOMEWHAT *OR* A LOT AND**
- **S1F = SOMEWHAT *OR* VERY LIKELY AND**
- **S1G = SOMEWHAT *OR* VERY LIKELY**

S3. What is your gender?

Male	o
Female	o

S4. What is the highest grade you have completed in school? *(Select one)*

Less than High School	o
High school	o
Some college or technical/vocational training	o
Four years of college (Bachelor's degree)	o
More than Bachelor's degree	o

S5a. Do you consider yourself to be of Hispanic, Latino, or Spanish origin?

Yes	o
No	o

S5b. What do you consider to be your race? *(Select all that apply)*

White	❒
African American / Black	❒
Asian	❒
Other	❒

PROGRAMMER:

1. **DISPLAY S5a AND S5b ON SAME SCREEN**

S6. Which of the following best describes your total household income?

Under $25,000	o
$25,000 to $49,999	o
$50,000 to $74,999	o
$75,000 to $99,999	o
$100,000 or more	o

S9. Earlier you indicated that you have used SNUS. Which of the following brands of SNUS have you used? *Select "yes" or "no" for each row.*

Have you used ...

SNUS	Yes	No
Camel	o	o
Copenhagen	o	o
General	o	o
General Swedish Variety	o	o
Grand Prix	o	o
Klondike	o	o
Marlboro	o	o
Nordic Ice	o	o
Skoal	o	o
Tourney	o	o
Triumph	o	o
Some other brand of SNUS	o	o

PROGRAMMER:

1. **ASK IF CURRENT OR FORMER SNUS USER**
2. **MUST SAY "YES" TO AT LEAST 1 ROW**

ARM ASSIGNMENT: CHECK QUOTAS TO SEE IF ELIGIBLE FOR EACH SURVEY ARM

ARMS:

Arm 1: Warning #1
Arm 2: Warning #2
Arm 3: Warning #3
Arm 4: Warning #4

IF ELIGIBLE FOR MORE THAN ONE ARM, ASSIGN WHERE NEEDED THE MOST TO BALANCE:

a) **Smoking status: Current, Former, Never**
b) **CURRENT/FORMER SNUS USERS**
c) **Has used Camel SNUS (S9 ROW 1 is "YES")**
d) **Demographics**
e) **Current Experimenters**
f) **Potential Quitters**

PROGRAMMER: CHECK QUOTAS AND INVITE IF ELIGIBLE

You have qualified for our survey, and we'd like to invite you to participate. The survey will require approximately 15 minutes to complete, and we ask for your undivided attention once you begin it. If you do not have 15 minutes right now, please click "Stop," and return any time during the next 24 hours when you have an uninterrupted 15 minutes.

Camel SNUS MRTP Comprehension & Perceptions Survey

–Survey –

This survey focuses on new information about an existing tobacco product. Everyone is asked all of the questions in this survey, regardless of whether or not they currently use tobacco.

Please take your time and review the information on the next few screens closely so that you will be able to answer the questions that follow.

PROGRAMMER:

1. **ASK ALL**

Please carefully review the product information below. Take as much time as you need. Please scroll down to view all of the product information and the questions which follow it.

[INSERT STIMULI BASED ON NAID LEAD DIGIT]

First, we are going to ask three questions about what the ad <u>says</u> and then we will ask some questions about what you <u>believe</u>.

Q1a. Please answer the following questions based on what the ad communicates to you (whether or not you believe the information).

Select one response per row.

		Yes	No	Don't know/Not Sure
1	Is quitting the best choice for a smoker who is concerned about the health risks from smoking?	o	o	o
2	Should adults who do not use or who have quit using tobacco products start using Camel SNUS?	o	o	o
3	Is Camel SNUS, which contains nicotine, addictive?	o	o	o

PROGRAMMER:

1. **ASK ALL**
2. **RANDOMIZE ROW ORDER**
3. **INSERT STIMULI ON SAME SCREEN**

Q1a2. According to the ad, what do smokers need to do in order to receive a health benefit from using Camel SNUS?

Select one.

Stop smoking completely and use Camel SNUS instead	o
Reduce their smoking by half and use Camel SNUS in addition	o
Not change their smoking habits, but use Camel SNUS as well	o
Don't know	o

PROGRAMMER:

1. **ASK ALL**
2. **INSERT STIMULI ON SAME SCREEN**
3. **RANDOMIZE APPEARANCE OF ROWS 1 AND 3**

Q1b. Now, what does the information communicate to you about the risk associated with Camel SNUS, regardless of if you believe the information or not?

Select one response per row.

		The information communicates that Camel SNUS has...			
		Same level of health risk as continuing to smoke	Less health risk than continuing to smoke, but has some risk	No health risk at all	I don't know/not sure
1	Lung cancer	o	o	o	o
2	Oral cancer	o	o	o	o
3	Respiratory disease	o	o	o	o
4	Heart disease	o	o	o	o

PROGRAMMER:

1. **ASK ALL**
2. **RANDOMIZE ROW ORDER**
3. **INSERT STIMULI ON SAME SCREEN**

SHOW ALL

We are interested in your beliefs related to various health risks associated with using different types of tobacco products.

Please estimate what impact using each type of tobacco has on a person's risk of developing each condition, using a 7-point scale where "1" means "No Risk" and "7" means "Substantial Risk".

Q2a. Please estimate what impact you believe using each type of tobacco has on a person's risk of developing lung cancer.

	No Risk ⇩						**Substantial risk ⇩**
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:

1. **ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT**

Q2b. Please estimate what impact you believe using each type of tobacco has on a person's risk of developing oral cancer.

	No Risk ⇩						**Substantial risk ⇩**
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:

1. **ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT**

Q2c. Please estimate what impact you believe using each type of tobacco has on a person's risk of developing respiratory disease.

	No Risk ⇩						**Substantial risk ⇩**
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:

1. **ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT**

Q2d. Please estimate what impact you believe using each type of tobacco has on a person's risk of developing heart disease.

	No Risk ⇩						**Substantial risk ⇩**
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:

1. **ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT**

Q2e. Please estimate what impact you believe using each type of tobacco has on a person's risk of developing generally poorer health.

	No Risk ⇩						**Substantial risk ⇩**
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:

1. **ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT**

Q2f. Now please rate how addictive you believe each of the following types of tobacco are, using a 7-point scale where "1" means "Not At All Addictive" and "7" means "Extremely Addictive".

	Not At All Addictive ⇩						**Extremely Addictive** ⇩
	1	2	3	4	5	6	7
Camel SNUS	❍	❍	❍	❍	❍	❍	❍
Cigarette smoking	❍	❍	❍	❍	❍	❍	❍
Smokeless tobacco use other than Camel SNUS (e.g., chewing tobacco, snuff, dissolvable tobacco, and other brands of SNUS. Smokeless tobacco does not include e-cigarettes.)	❍	❍	❍	❍	❍	❍	❍

PROGRAMMER:
ASK ALL AND SHOW ALL 3 ROWS AND ALL TEXT

Q2g. Does Camel SNUS reduce the risk of other smoking-related diseases that are not discussed in the ad?

Yes	o
No	o
Don't know	o

PROGRAMMER: ASK ALL

Now we are interested in your perceptions of various types of health risks associated with using CAMEL SNUS relative to using smoking cessation aids (e.g., gum, patches and lozenges) and quitting tobacco entirely instead of continuing to smoke.

Q5a. Do you believe the following statement is true, false, or you don't know?

Camel SNUS is NOT a safer alternative than products that are used to quit tobacco such as gum, patches, and lozenges.

True	o
False	o
Don't know	o

Q5b. Do you believe the following statement is true, false, or you don't know?

Camel SNUS is NOT a safer alternative than quitting tobacco entirely.

True	o
False	o
Don't know	o

PROGRAMMER:

1. **ASK ALL**
2. **SHOW Q5a AND Q5b ON SAME SCREEN**

The remaining questions are not about tobacco. These questions are to help us get a better sense of who you are and how you make decisions about your health. The information below is from the back of a container of a pint of ice cream. Please use this information to answer the following questions.

Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

PROGRAMMER:

1. **ASK ALL**

6a. If you eat the entire container, how many calories will you eat?

_____ Calories

PROGRAMMER:

1. **ASK ALL**
2. **SHOW LABEL ON SAME SCREEN**

6b. If you are allowed to eat 60 grams of carbohydrates as a snack, how many cups of ice cream could you have?

_____ Cups

PROGRAMMER:

1. **ASK ALL**
2. **SHOW LABEL ON SAME SCREEN**

6c. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?

_____ Grams

PROGRAMMER:

1. **ASK ALL**
2. **SHOW LABEL ON SAME SCREEN**

6d. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?

_____ %

PROGRAMMER:

1. **ASK ALL**
2. **SHOW LABEL ON SAME SCREEN**

For the next few questions, pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

6e. Is it safe for you to eat this ice cream?

Yes	o
No	o

PROGRAMMER:

1. **ASK ALL**
2. **SHOW LABEL ON SAME SCREEN**

6f. Why isn't it safe to eat this ice cream? *(Select one.)*

It is high in calories	o
It contains peanut oil	o
It is high in fat	o
The ice cream container is coated with latex	o
People who are allergic to penicillin should not eat ice cream	o

PROGRAMMER:

1. **ASK IF 6E IS "NO"**
2. **SHOW LABEL ON SAME SCREEN**

Please note that the goal of this survey is only to assess how clearly the risks associated with tobacco products are communicated. It is **not** intended to encourage you or anyone else to continue/start using tobacco products.

- Individuals should consider the conclusions of the U.S. Surgeon General, the Centers for Disease control, and other public health and medical officials when making decisions regarding smoking.
- The best course of action for tobacco users concerned about their health is to quit.
- Minors should never use tobacco products and adults who do not use or have quit using tobacco products should not start.
- Adults who smoke should avoid exposing minors to secondhand smoke, and adult smokers should comply with rules and regulations designed to respect the rights of other adults.

PROGRAMMER:

1. **ASK ALL**

All information contained in this advertising is provided for your information only and for regulatory research purposes only. In order to advertise that a smokeless tobacco product is less harmful than a cigarette or another smokeless tobacco product, the company must first obtain clearance from the Food and Drug Administration ("FDA"). As part of that clearance process, a company must present evidence demonstrating that consumers perceive and understand the statements that the company is making about the product in its proposed advertising. This research is aimed at developing advertising that will achieve this. The advertisements used in this research study have not and will not be used by the company to promote its products commercially without first obtaining clearance from FDA to do so.

The information and opinions expressed here are believed to be accurate, based on sound science and the best judgment available to the company. However, no action or inaction should be taken based on the contents of this information; instead, you should consult appropriate health professionals on any matter relating to your health.

THANK YOU SCREEN

PROGRAMMER: ASK ALL

TABLE 1: TOTAL= 7,500

Additional quotas: Experimenters = ~100 and Potential Quitters = ~100

	Current Tobacco User	Former Tobacco User	Never-Tobacco User
	2,500	**2,500**	**2,500**
Northeast	350 – 500	350 – 500	350 – 500
Midwest	450 – 650	450 – 650	450 – 650
South	750 – 1,000	750 – 1,000	750 – 1,000
West	450 – 650	450 – 650	450 – 650
18-30	650 – 800	300 - 400	650 – 800
31-50	950 – 1,100	800 – 950	950 – 1,100
51+	650 - 800	1,150 – 1,300	650 - 800
Male	1,127 – 1,377	1,127 – 1,377	1,127 – 1,377
Female	1,127 – 1,377	1,127 – 1,377	1,127 – 1,377
Hispanic	327 – 427	327 – 427	327 – 427
Non-Hispanic - White	1,500 – 1,750	1,500 – 1,750	1,500 – 1,750
Non-Hispanic - Black	250 – 350	250 – 350	250 – 350
Non-Hispanic - Asian/Other	177 – 250	177 – 250	177 – 250
Up to High School	1,200 – 1,350	850 – 1,000	800 – 950
Some College	650 – 800	650 – 800	600 – 750
Bachelor's Plus	400 – 550	750 – 900	850 – 1,000

Northeast
Connecticut
Maine
Massachusetts
New Hampshire
Rhode Island
New Jersey
New York
Pennsylvania
Vermont

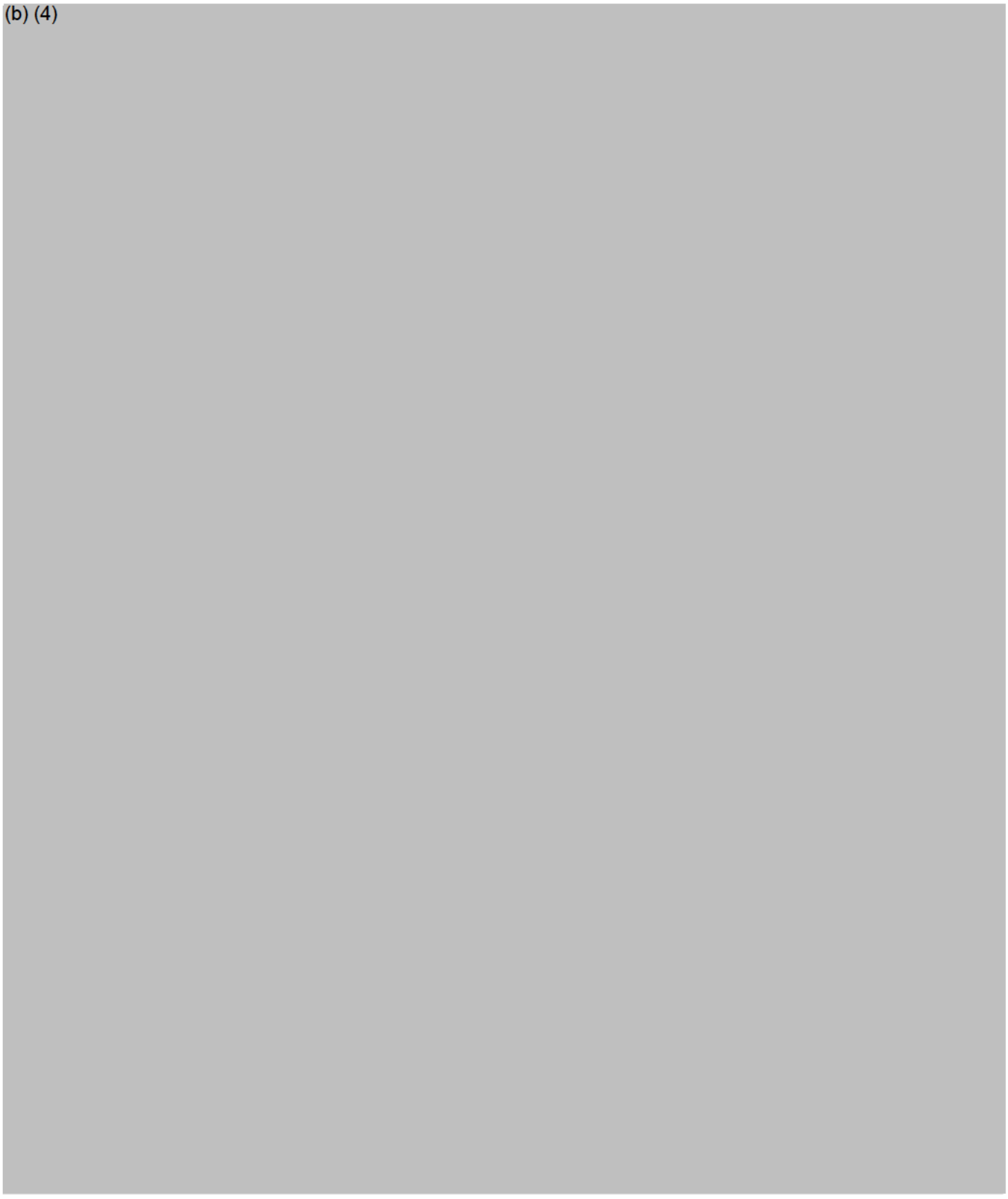
Midwest
Indiana
Illinois
Iowa
Kansas
Michigan
Minnesota
Missouri
Nebraska
North Dakota
Ohio
South Dakota
Wisconsin

South
Alabama
Arkansas
Delaware
District of Columbia
Florida
Georgia
Kentucky
Louisiana
Maryland
Mississippi
North Carolina
Oklahoma
South Carolina
Tennessee
Texas
Virginia
West Virginia

West
Alaska
Arizona
California
Colorado
Hawaii
Idaho
Montana
Nevada
New Mexico
Oregon
Utah
Washington
Wyoming

Appendix B: Camel SNUS MRTP Comprehension and Perception Stimuli

(b) (4)



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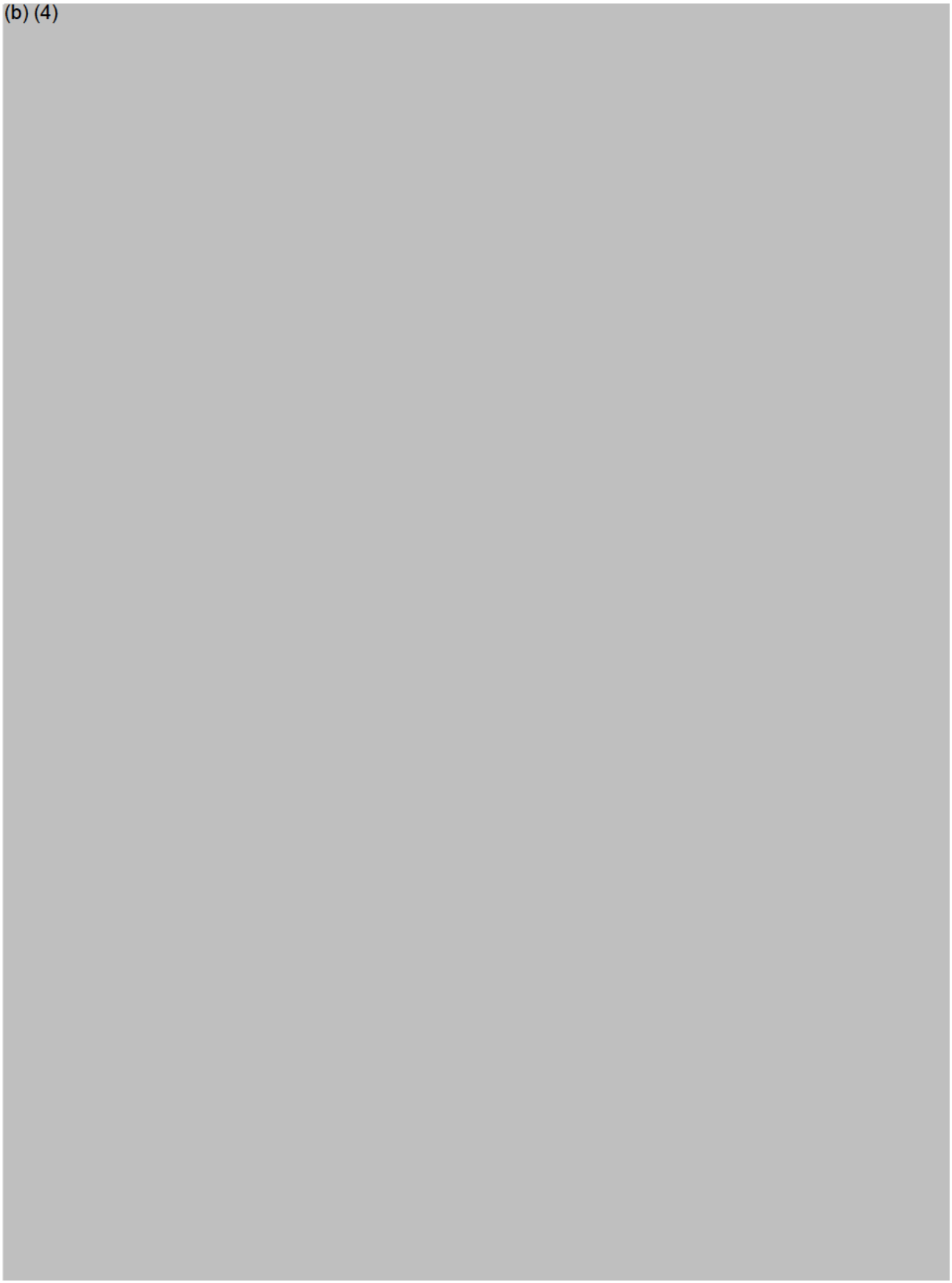

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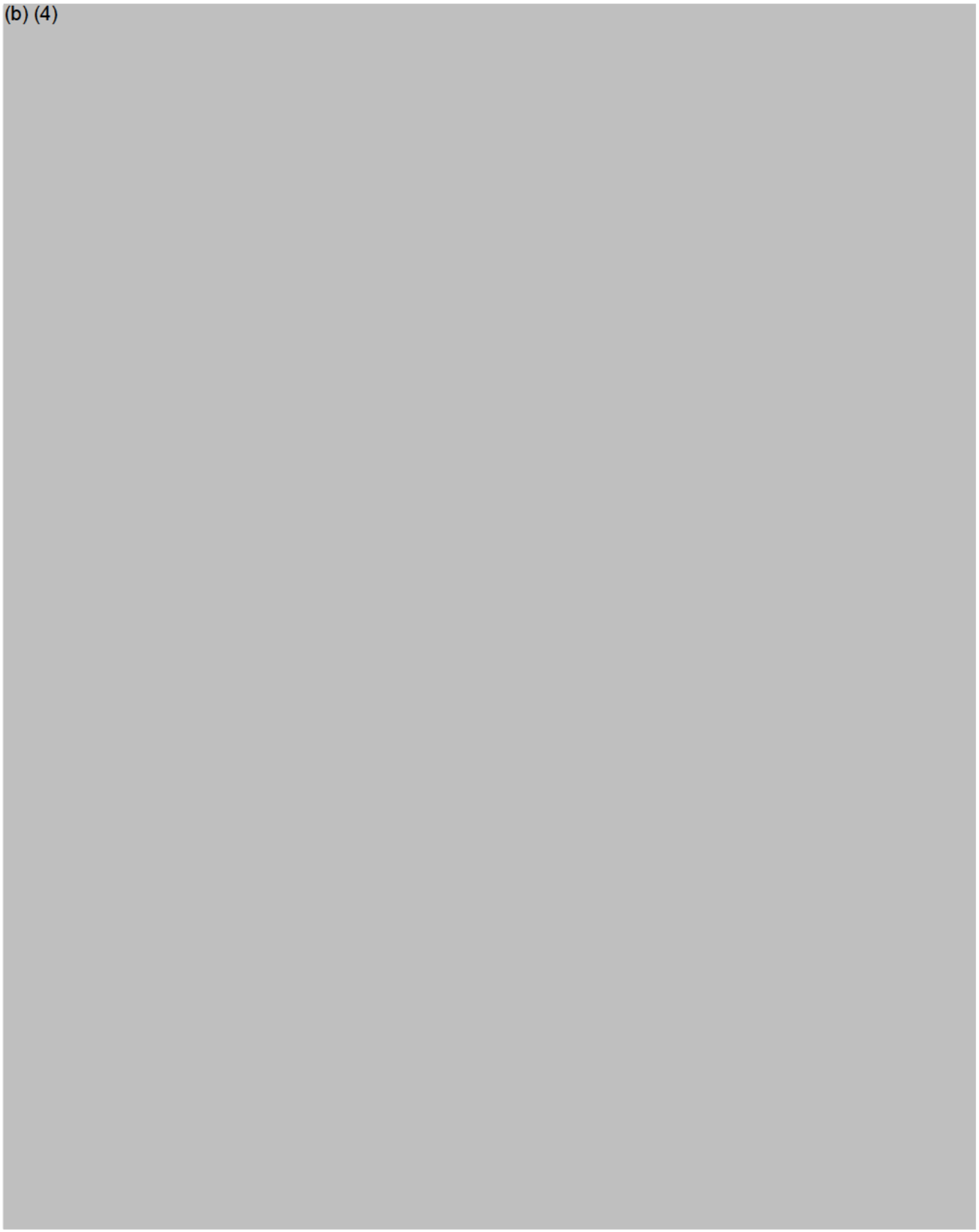

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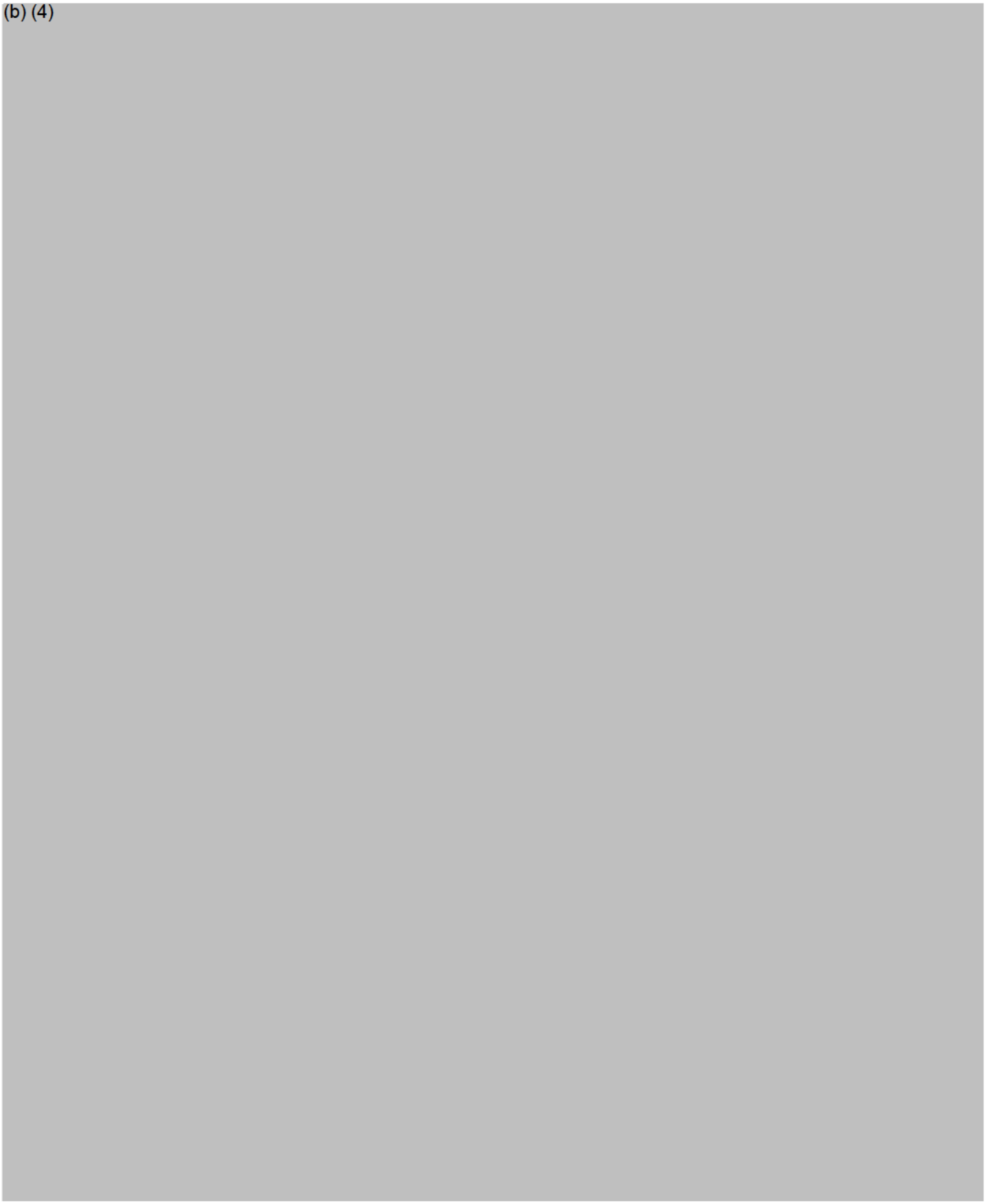

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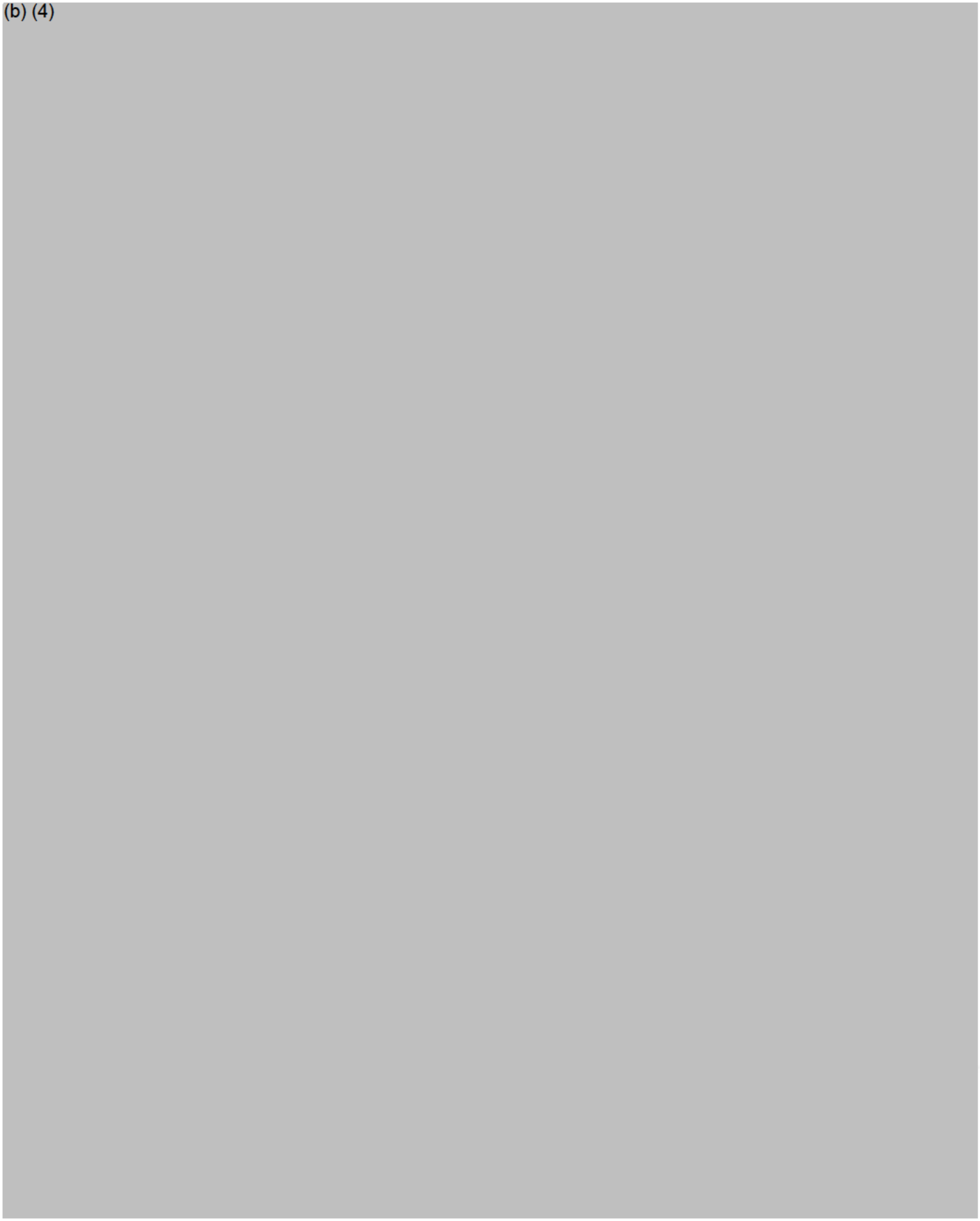

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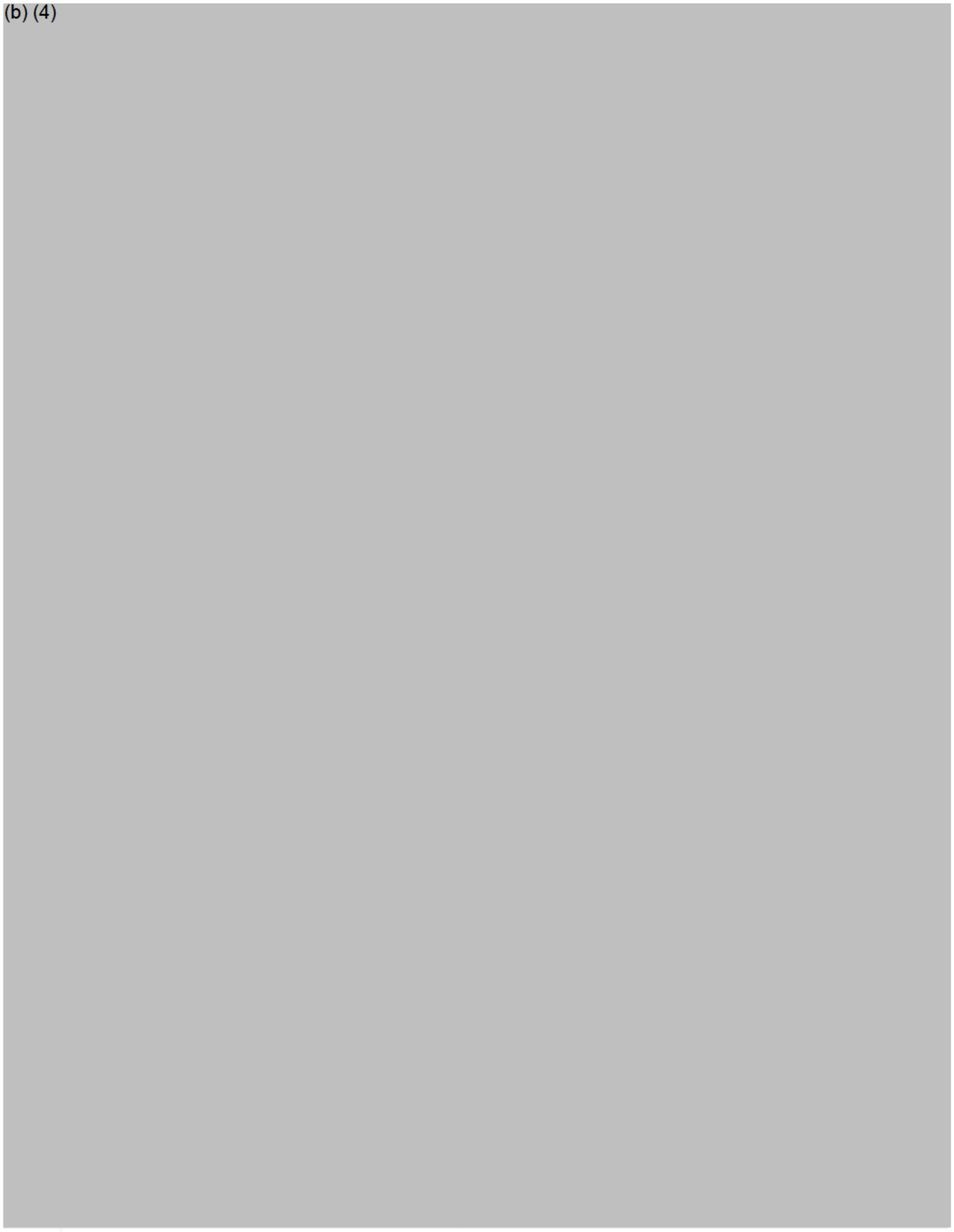

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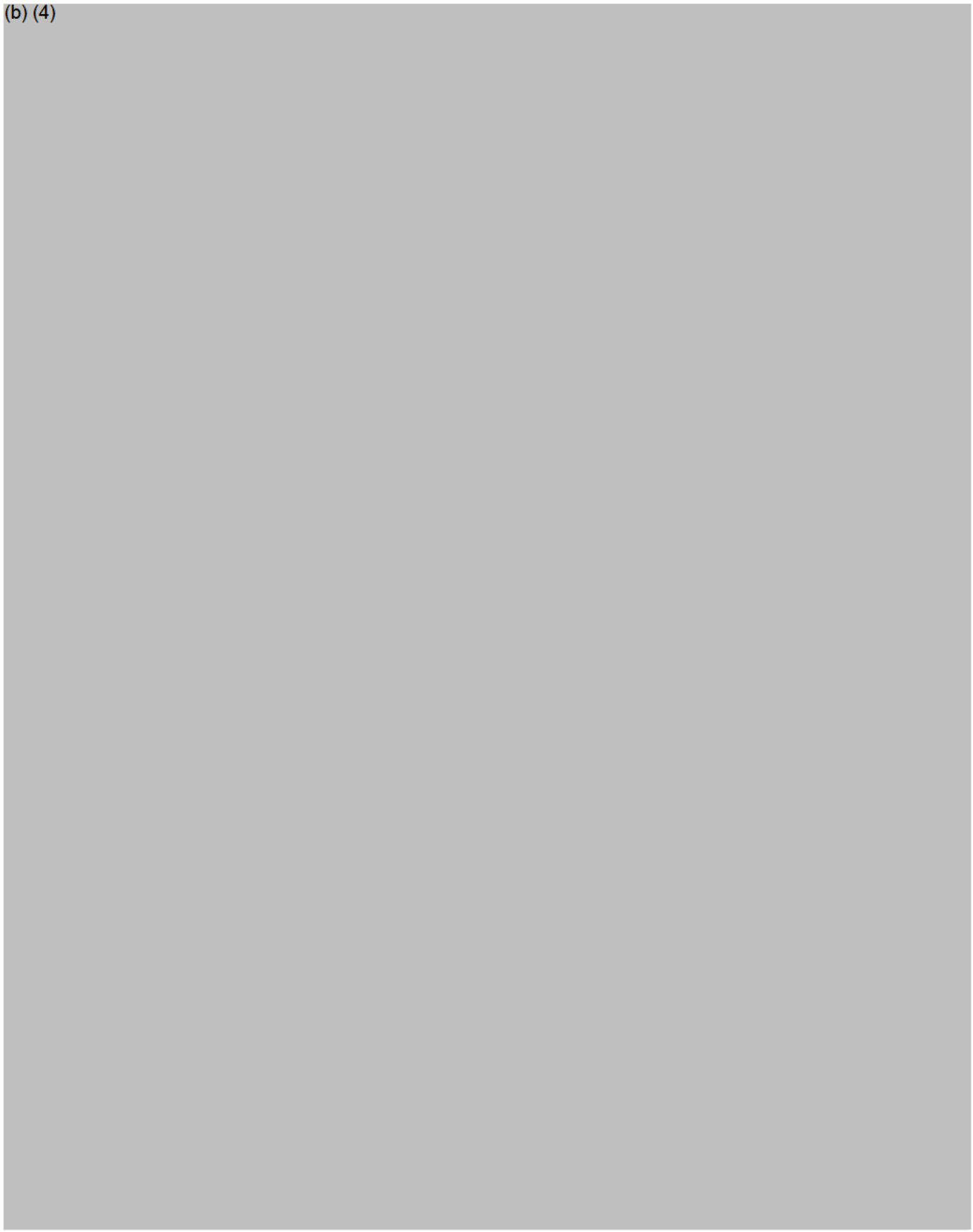

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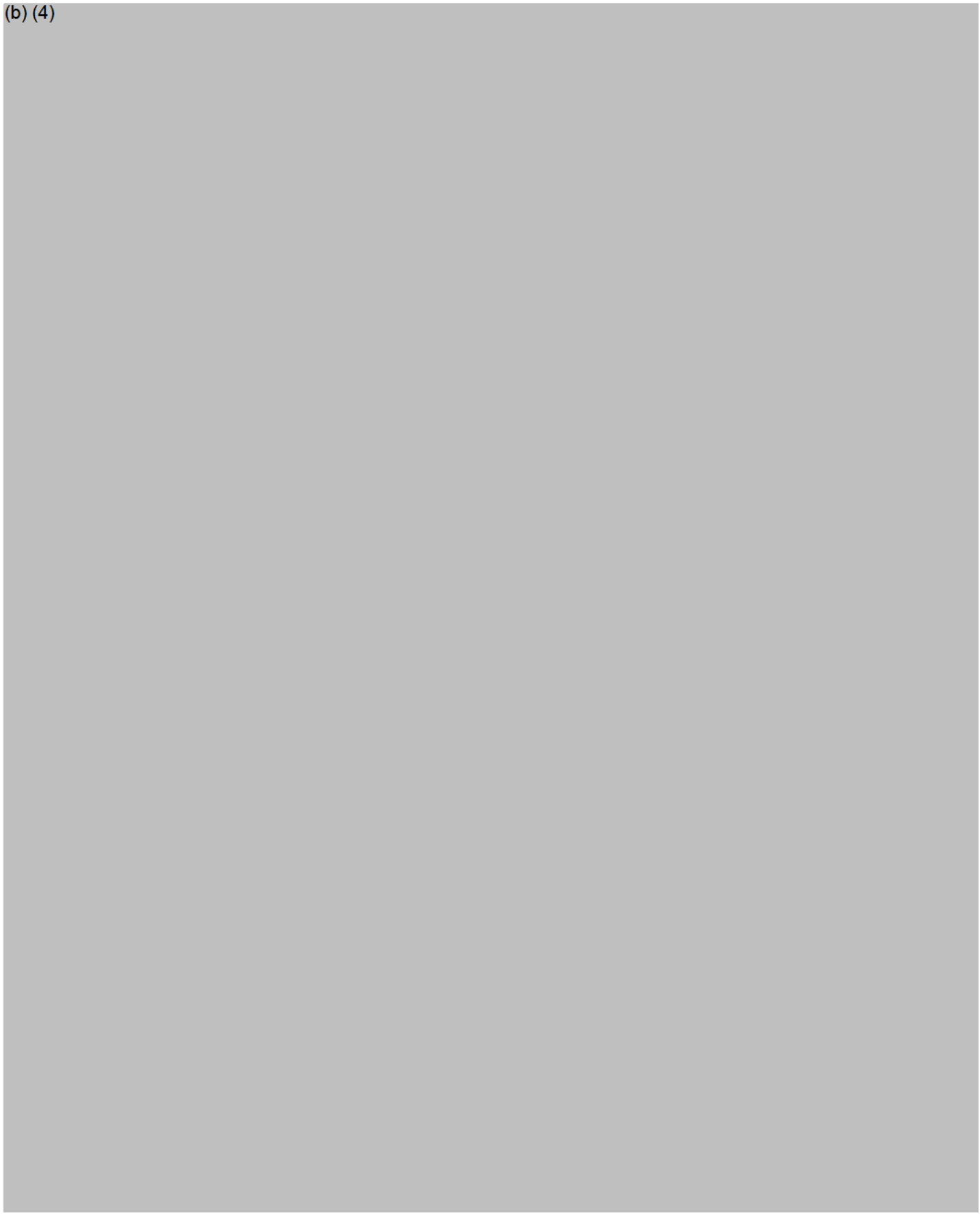

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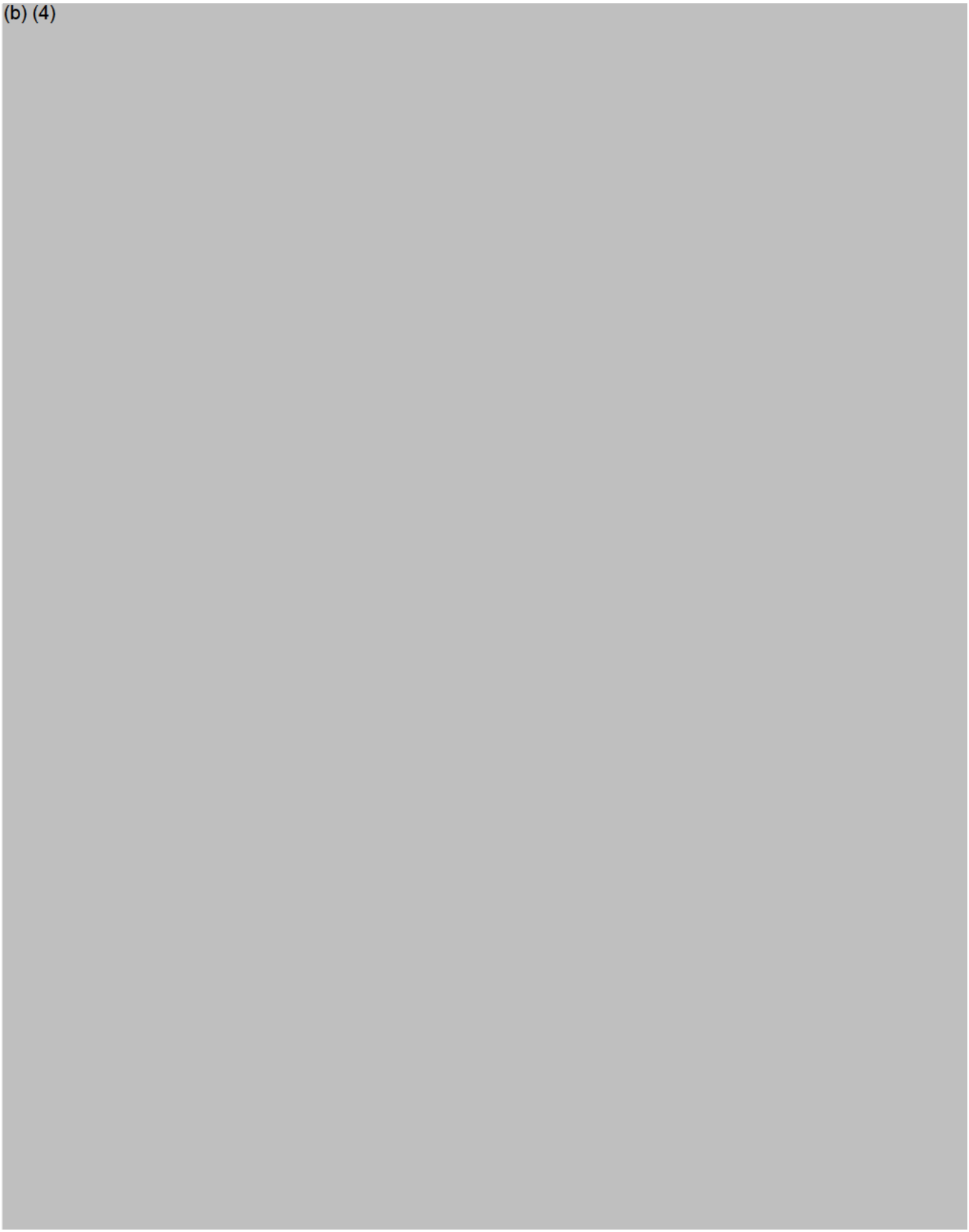

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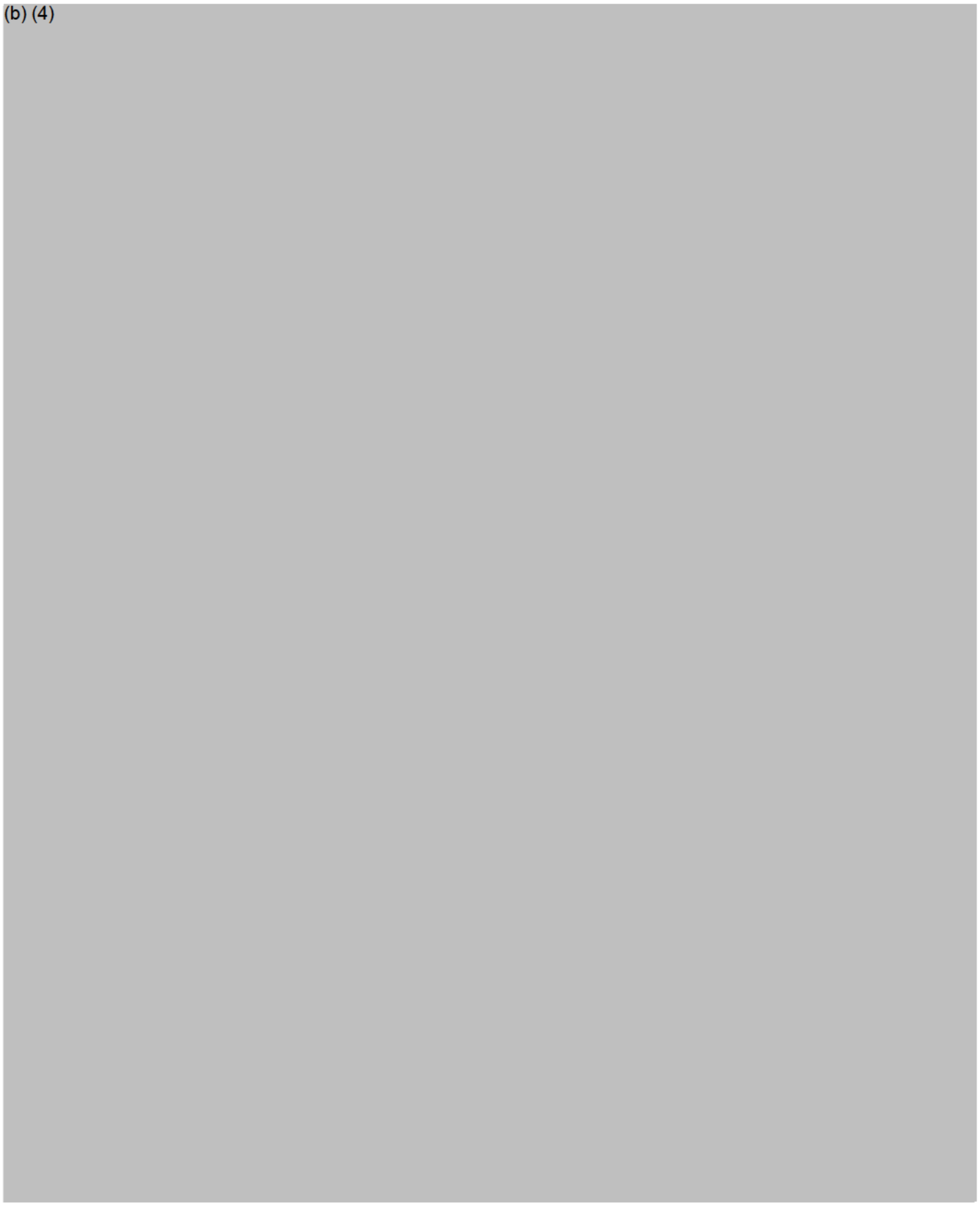

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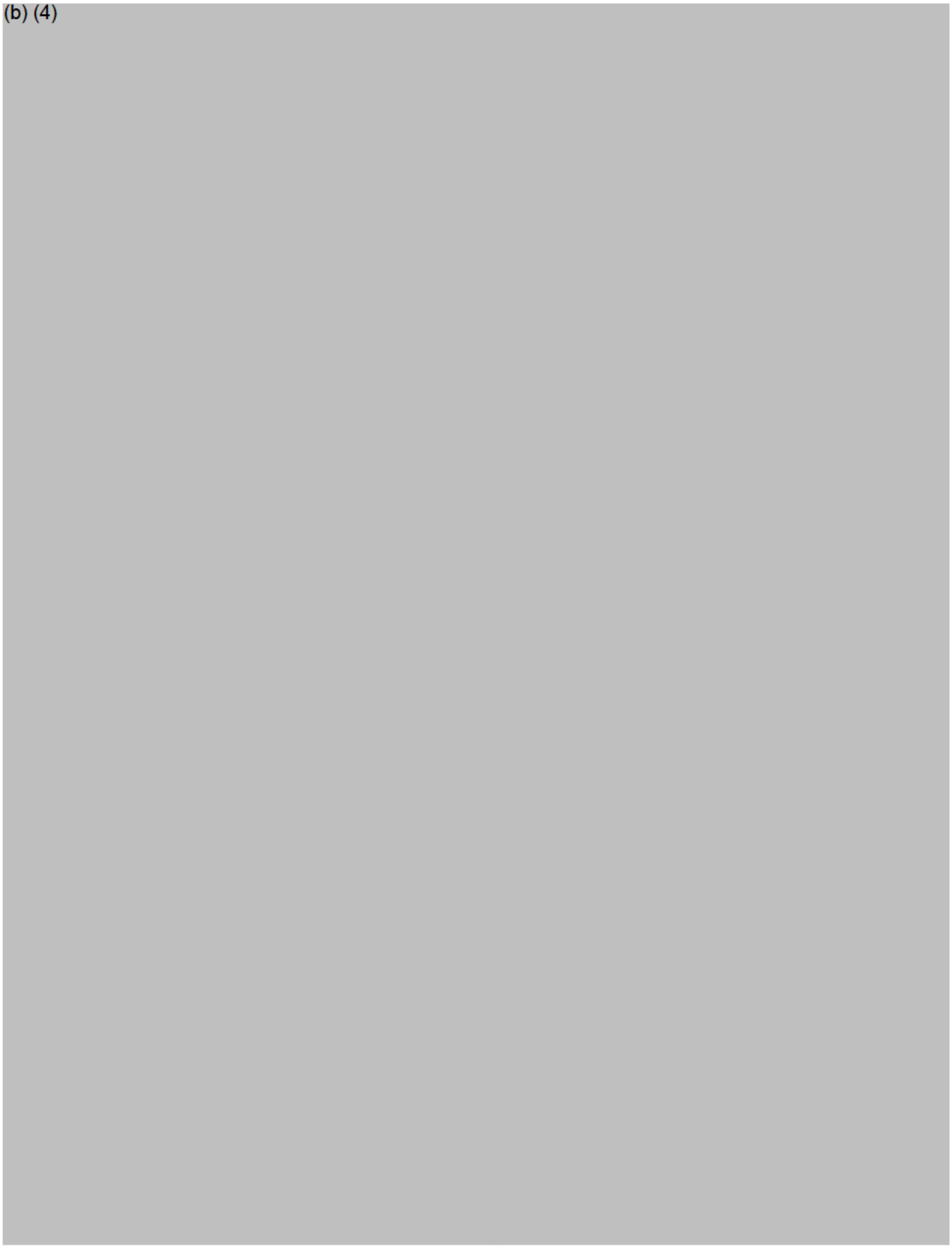

(b) (4)