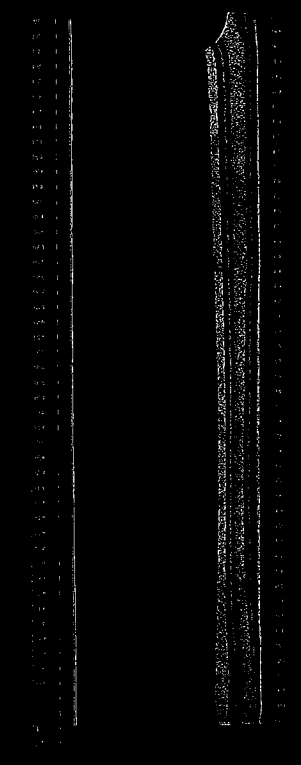


# Policy on Promotional Activities

Effective Date: December 4, 2006

In the promotion of our products, AstraZeneca commits to engage in proper, ethical and legal practices in all aspects of its business including representations made to health care professionals (HCPs), patients and purchasers.

## Policy Statement

All AstraZeneca promotional activities must be compliant with the requirements set forth in the Federal Food, Drug, and Cosmetic Act, the PhRMA Code, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers and all other codes of marketing practice, laws and regulations governing the pharmaceutical industry in the United States.

To achieve this objective, it is AstraZeneca policy that:

- All information supporting promotional activities:
  - Must be accurate and not misleading;
  - Must only make claims when supported by substantial clinical evidence;
  - Must reflect balance between risks and benefits;
  - Must be consistent with the FDA-approved labeling.
- All promotional activities must be consistent with high ethical standards.
- Promotional activities directed towards healthcare professionals must be designed to help HCPs improve treatment of and services to patients
- Any information provided to a healthcare professional that is not within the FDA-approved labeling may only be provided in response to an unsolicited request by the healthcare professional.
- All materials used for promotional purposes must be reviewed and approved through the eSTaR process prior to use with any audience.
- Meals, in connection with promotional activities, may be provided to healthcare professionals so long as they are modest (as judged by local standards).
- No entertainment or recreational events shall be provided in conjunction with promotional activities, unless otherwise specified
- Compensation paid to HCPs for services shall not be in consideration of, as an inducement to, or in return for the current or future prescribing, purchasing, use, formulary inclusion or favorable position, or dispensing of AZ products.

It is the responsibility of all individuals engaged in promotional activities to ensure that their actions are in line with all applicable policies, laws, codes and regulations.

# Standards for Engaging in Product Promotion

## 1 Introduction

AstraZeneca (AZ) commits to provide healthcare professionals (HCPs) with accurate information regarding the approved uses of its products to ensure that products are used appropriately for the benefit of patients.

## 2 Purpose

This document is a mandatory supporting document to the Policy on Promotional Activities. It sets forth clear standards that must be adhered to by all AstraZeneca employees engaging in any type of product promotion.

## 3 Scope

This document applies to all AstraZeneca employees engaging in any type of product promotion.

## 4 Definitions

**Healthcare Professional (HCP):** Any person who exercises skill or judgment or provides a service relating to the preservation or improvement of patient health or the treatment or care of individuals related to disorders within the AstraZeneca portfolio. This includes, but is not limited to, hospital consultants, physicians, physician's assistants, pharmacists, nurses, nurse practitioners, social workers and practice administrators.

**Prescribing Information (PI):** The full prescribing information (also called package insert, product circular, full disclosure, or directions for use) is the basis for all of the company's communications about its products. It sets forth the FDA-approved conditions for use of a product, including indications, dosages and patient populations, as well as warnings, contraindications and adverse events.

## 5 Compliance Standards

## 5.1 General Principles

### 5.1.1 Conformance to Full Prescribing Information

AstraZeneca employees engaged in a product promotion discussion with HCPs must ensure that the discussion conforms to the FDA-approved prescribing information (PI).

When engaging in a product discussion with an HCP, AZ employees are acting as agents of AstraZeneca. AZ may be responsible for, and bound by, any statements or promises made by the employee. Any claim made orally that does not conform to the product's full prescribing information, may render the product misbranded and could jeopardize AZ's ability to market that particular product. Also, statements extending claims or minimizing risks may expose AZ to product liability claims. Therefore, AZ employees must stay strictly within approved claims and never minimize any of the risks associated with the use of any AZ product.

***i A Copy of the Current PI for Each Product Discussed Must Be Offered***

A copy of the current full PI for each product discussion initiated must be offered, including discussions in which there are references to non-leave-behind promotional materials. If the HCP initiates a discussion about a product that the AZ employee was not planning to discuss and for which no current full PI is at hand, the AZ employee must offer to obtain a copy.

***ii Off-Label Issues May Only Be Addressed By Submitting a Professional Information Requests (PIR)***



If an HCP mentions a use of a product that is not an approved indication, or mentions using it in ways not recommended in the full PI (such as administering the product in higher-than-recommended dosages), the AZ employee must clearly state that the product is not indicated for use in that way and

provide a copy of the current full PI. If the HCP indicates that he or she would like further information about such usage, the employee should offer to assist the HCP in submitting a Professional Information Request (PIR).

***iii Balanced Presentation***

AZ employees must also give an objective and balanced presentation of both the benefits and risks of the product. This means that AZ employees must make sure that the sum total of their presentations to any HCP on a given product adds up to full awareness of the product's benefits and the risks associated with its use.

While not exhaustive, the following list sets forth some examples of activities ***that must be strictly avoided:***

- Making statements that tend to diminish the warnings in the full prescribing information. Example: "*As you know, Doctor, with almost any drug, hematological problems might result, but they usually don't*";
- Presenting a side effect as if it were a clinical benefit;
- Failing to point out the limits of a product's indications when the HCP advises you that he or she is using, has used, or intends to use the product beyond its claim structure;
- Marking up promotional materials or reprints. Highlighting, marking, or underlining points the AZ employee wishes to stress could be construed as an attempt to distract attention from or diminish information that the HCP should know
- Lifting statements out of context from the full prescribing information or approved promotional materials in any way that might distort their meaning;
- Abbreviating your discussion, because of an interruption or other constraints, after covering only the benefits or advantages of a product and not offering to leave a copy of the full prescribing information with the HCP.

If a product is simply mentioned in passing without reference to any indication, there is no requirement to give a complete, balanced statement or to offer the prescribing information. However, if such a mention leads to further discussion of the product, then the provisions of this document must be followed.

**5.1.2 Promotional Materials**

***i* Promotional materials must be used in a way that is consistent with the relevant full prescribing information and within the framework of a balanced presentation.**

***ii* Promotional Materials Must Be eSTaR-approved Prior to Use**

All materials used in promotion – including reprints, referenced texts, patient education pieces, display/exhibit materials and reminder items – must have prior approval through the eSTaR process.

- Homemade materials must never be used for promotion. Examples of homemade materials/activities include:
- Selectively editing eSTaR-approved materials;
- Distributing non-eSTaR-approved journal articles or reference texts;
- Writing notes to HCPs containing product information;
- Using eSTaR-approved materials outside the scope of its intended use;

- Providing copies of non-leave-behind promotional materials to HCPs;
- Providing copies of leave-behind materials that have been underlined, highlighted, annotated or otherwise marked;
- Distributing information available in the public domain that has not been eSTaR-approved for promotional use.

***iii*** **Promotional Materials Used Must Be Current Version**

All materials used in promotion must be currently eSTaR-approved and must be used in accordance with the guidance or directions accompanying the materials, including directions about dates of use. Employees must never use materials that are expired or materials that the employee has been instructed to discontinue using.

5.1.3 **Comparisons with Competitive Products**

***i*** **Employees May Not Initiate Any Discussion Involving Comparisons With Competitive Products Unless Specifically Instructed To Do So.**

In such case, approved materials and training will be provided to the employee. As with all product discussions, all such product comparisons may be made only in the context of an objective, balanced presentation. The benefits of one product and the shortcomings of another may not be singled out.

***ii*** **Unsanctioned Product Comparison Issues May Only Be Addressed By Submitting a Professional Information Request (PIR)**

If asked a question requiring a product comparison, where the AZ employee has not been provided with approved materials and training, offer to assist the HCP in obtaining information through a PIR.

***iii*** **Misunderstandings on the Part of an HCP Regarding a Competitive Product That Does Not Involve Safety, Efficacy, And/Or Tolerability (E.g., Dosing Frequency) Should Be Resolved Using That Product's Current Prescribing Information.**

Any such reference must offer only a factual accounting of points in the full prescribing information. If the AZ employee must refer to another company's full prescribing information, the employee must take reasonable precautions to ensure that it is current. Full prescribing information in the latest edition of the Physician's Desk Reference or in its most recent supplements, generally, may be assumed to be current. Of course, if the employee has actual knowledge or reason to believe that the prescribing information is not current, he/she may not use that source.

REDACTED

REDACTED

REDACTED

REDACTED

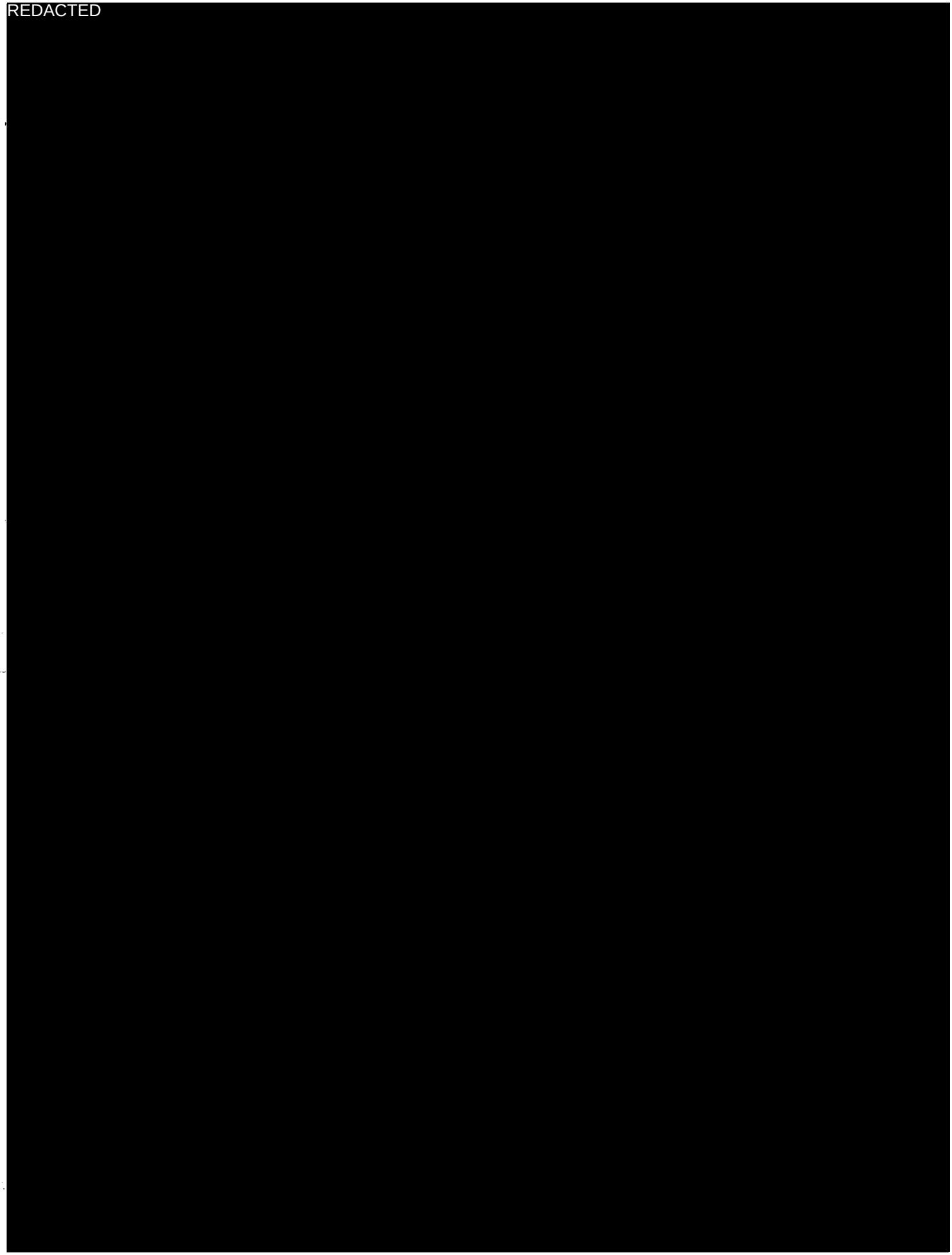
REDACTED

REDACTED

REDACTED

REDACTED

REDACTED



REDACTED

REDACTED

REDACTED

[redacted]

REDACTED

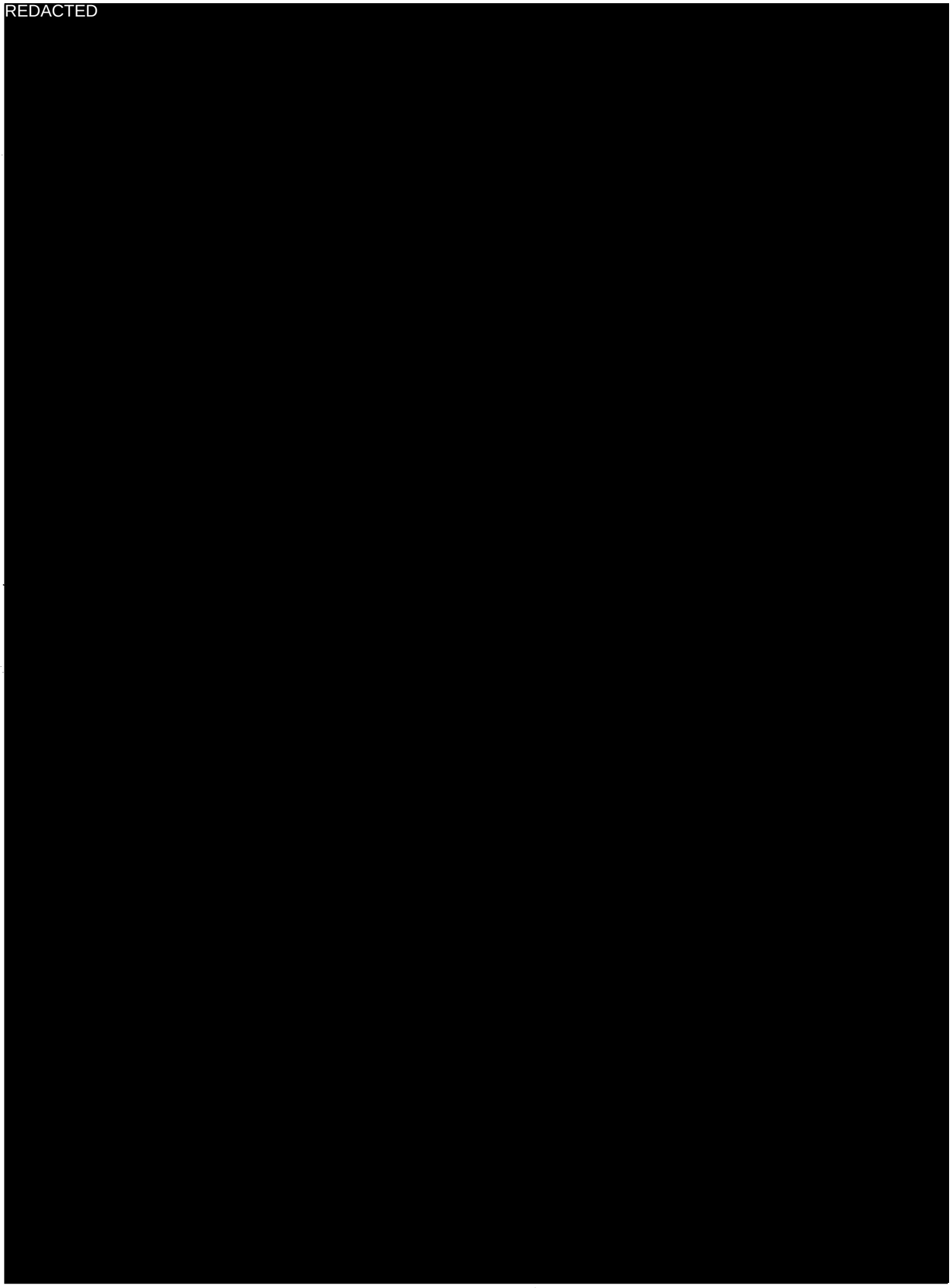
REDACTED

REDACTED

REDACTED

REDACTED

REDACTED



REDACTED

REDACTED

REDACTED

REDACTED

[redacted]

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

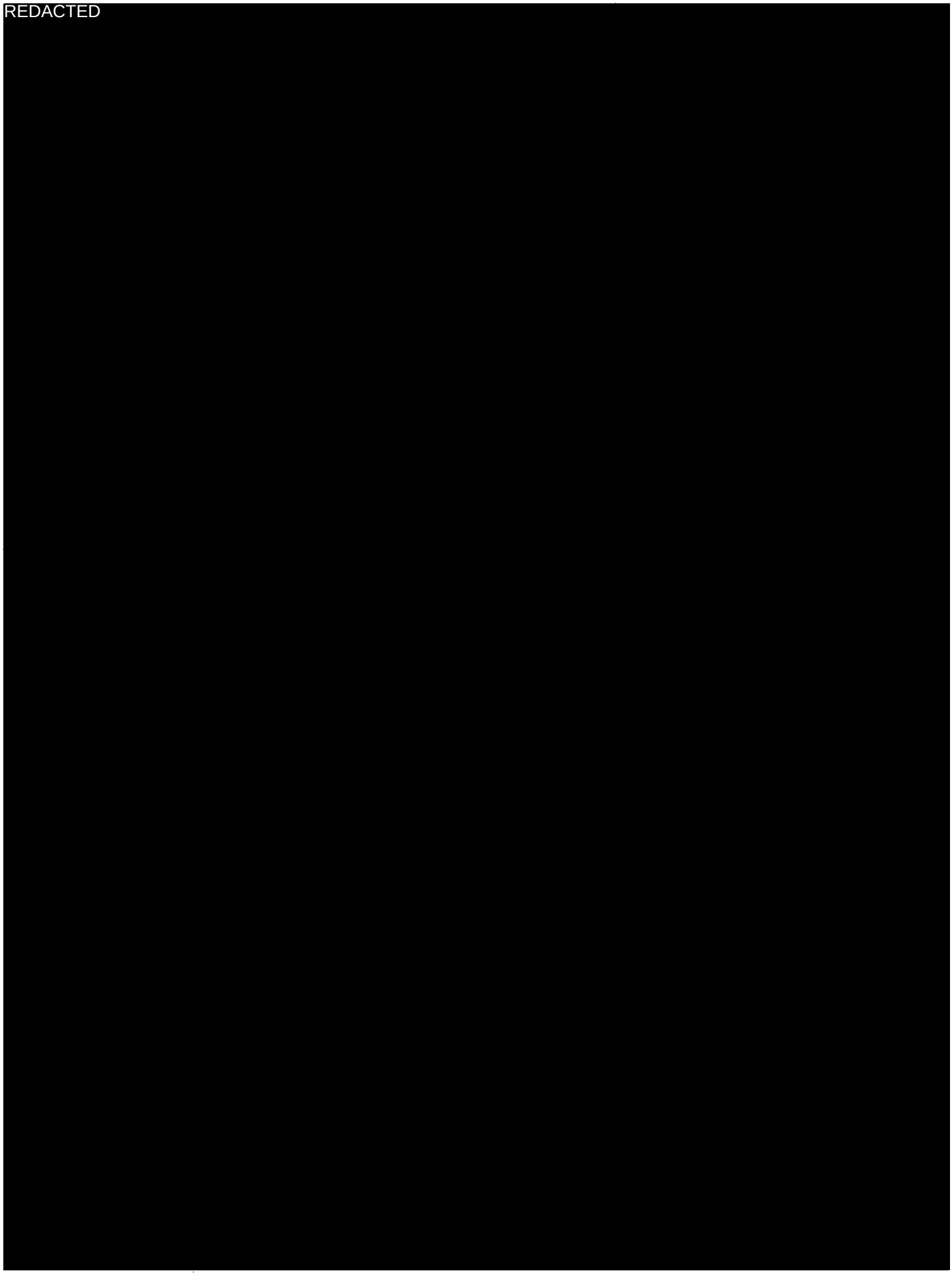
REDACTED

REDACTED

REDACTED

REDACTED

REDACTED



REDACTED

REDACTED

REDACTED

[redacted]

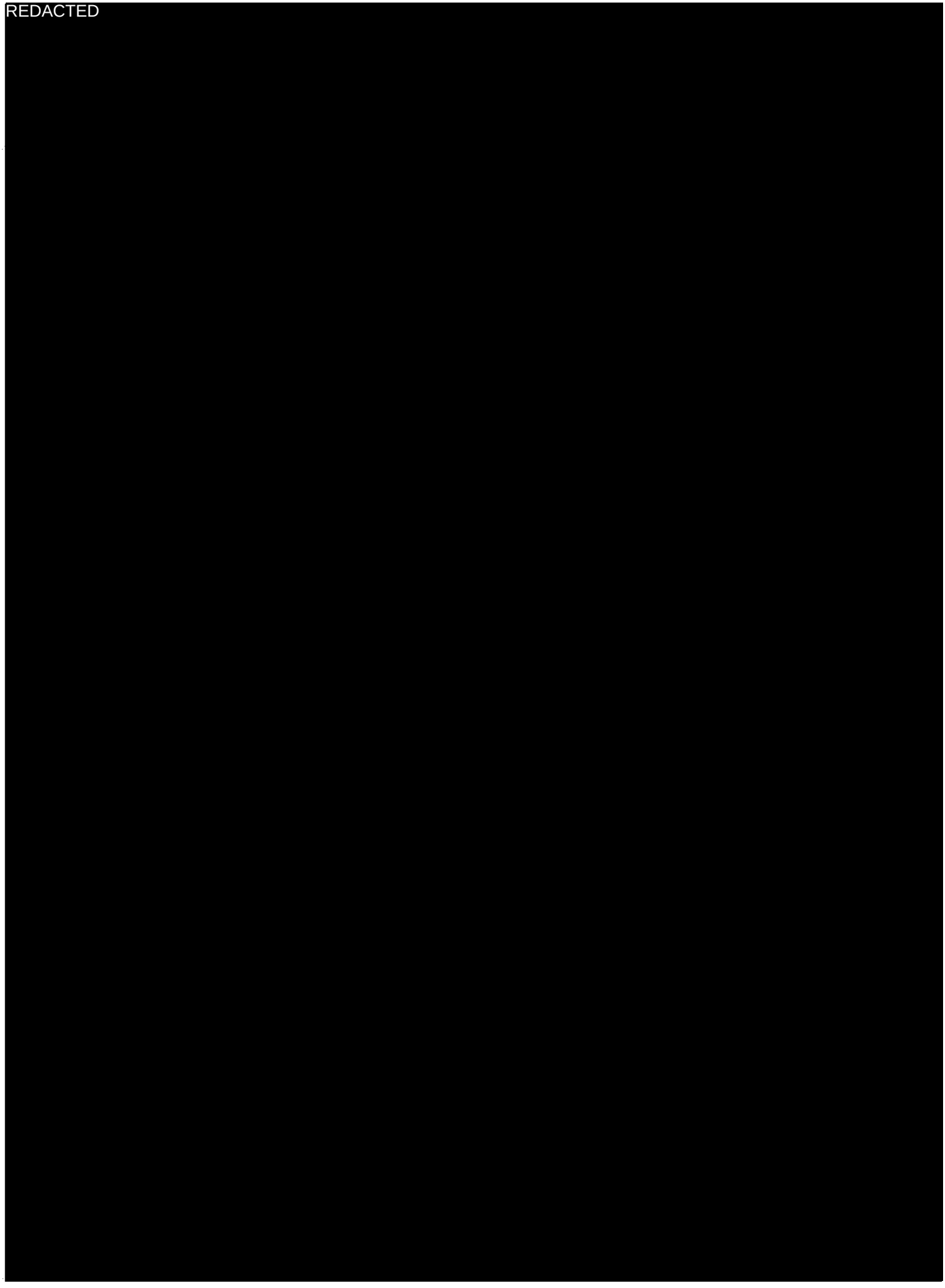
REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

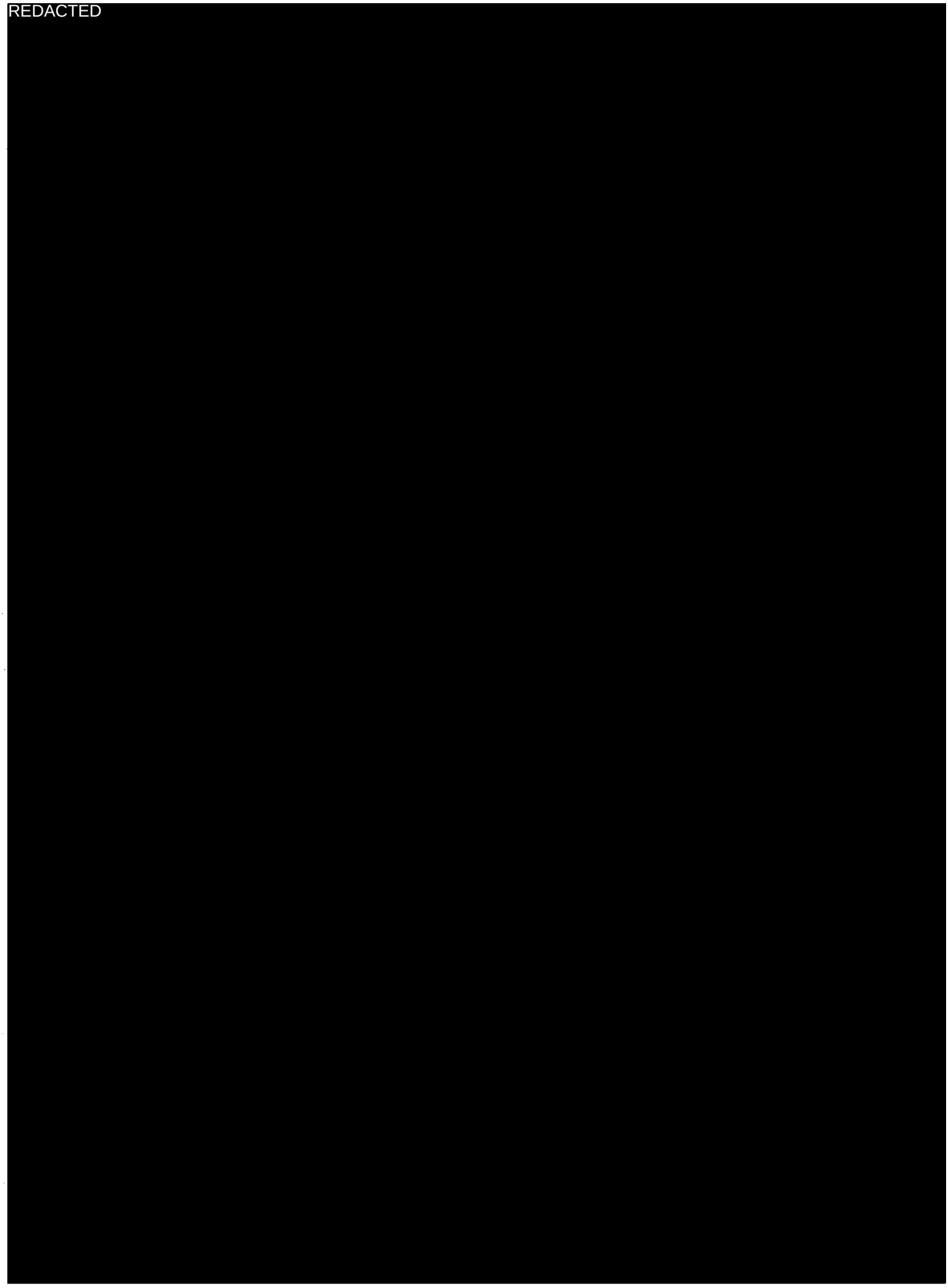


REDACTED

REDACTED

REDACTED

REDACTED



REDACTED

[redacted]

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

[redacted]

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED